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Go to the classic website

Record 1 of 1

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study-basics/learn-about-studies).

COMPLETED

Tofacitinib Ointment For Chronic Plaque Psoriasis

ClinicalTrials.gov ID NCT01831466

Sponsor Pfizer

Information provided by Pfizer (Responsible Party)

Last Update Posted 2015-11-25

Study Details Tab

Study Overview

Brief Summary

The study is beng done to test if tofacitinib ointment is safe and effective for people with plaque psoriasis. Two dose strengths of tofacitinib ointment (20 mg/g and 10 mg/g) applied once or twice daily are being tested. The safety and effectiveness of tofacitinib ointment used for 12 weeks will be compared to the safe and effectiveness of placebo ointment (vehicle) used for 12 weeks.

Official Title

Feedback

A Phase 2b, Multi-site, Randomized, Double-blind, Vehicle-controlled, Parallel-group Study Of The Efficacy, Safety, Local Tolerability And Pharmacokinetics Of 2 Dose Strengths And 2 Regimens Of Tofacitinib Ointment In Subjects With Chronic Plaque Psoriasis.

Conditions

Psoriasis Vulgaris Psoriasis

Intervention / Treatment

- Drug: tofacitinib ointment 20 mg/g
- Drug: tofacitinib ointment 10 mg/g
- Drug: placebo ointment (vehicle)
- Drug: tofacitinib ointment 20 mg/g
- Drug: tofacitinib ointment 10 mg/g
- Drug: placebo ointment (vehicle)

Other Study ID Numbers

- A3921082
- 2012-005645-20 (EudraCT Number)

Study Start

2013-05

Primary Completion (Actual)

2014-09

Study Completion (Actual)

2014-09

Enrollment (Actual)

476

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic-graft-versus-host-disease)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Tofacitinib (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype_human&query_Tofacitinib) Tofacitinib citrate (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype_human&query_Tofacitinib+citrate)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Arkansas Locations

Hot Springs, Arkansas, United States, 71913
Burke Pharmaceut ca Research

California Locations

Bakersfield, California, United States, 93304
Bakersfie d Dermato ogy and Sk n Cancer Med ca Center

Irvine, California, United States, 92697

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study-basics/learn-about-studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Have mild, moderate or severe plaque psoriasis (psoriasis vulgaris) for at least 6 months prior to Baseline
- At Baseline, have plaque psoriasis covering 2% to 20% of total body surface area (BSA) on the trunk and limbs (excluding palms, soles, and nails)
- If received certain treatments, should be off treatment for a minimum period of time (washout)

Exclusion Criteria:

- Currently have non-plaque forms of psoriasis or drug-induced psoriasis
- Require treatment with or cannot stop medication(s) prohibited during the study
- Have certain laboratory abnormalities at Baseline
- Current or history of certain infections
- Females who are pregnant, breastfeeding, or are of childbearing potential not using highly effective contraception

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Treatment Group A	Drug: tofacitinib ointment 20 mg/g • tofacitinib ointment 20 mg/g BID (twice daily) for 12 weeks
Experimental: Treatment Group B	Drug: tofacitinib ointment 10 mg/g • tofacitinib ointment 10 mg/g BID (twice daily) for 12 weeks
Placebo Comparator: Treatment Group C	Drug: placebo ointment (vehicle) • placebo ointment (vehicle) BID (twice daily) for 12 weeks
Experimental: Treatment Group D	Drug: tofacitinib ointment 20 mg/g • tofacitinib ointment 20 mg/g QD (once daily) for 12 weeks
Experimental: Treatment Group E	Drug: tofacitinib ointment 10 mg/g • tofacitinib ointment 10 mg/g QD (once daily) for 12 weeks
Placebo Comparator: Treatment Group F	Drug: placebo ointment (vehicle) • placebo ointment (vehicle) QD (once daily) for 12 weeks

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Achieving a PGA-C Response of Clear (0) or Almost Clear (1) and Greater Than or Equal to (≥) 2 Grade/Point Improvement From Baseline at Week 12	Clinical signs of plaque psoriasis (erythema [E], induration [I], and scaling [S]) were scored separately according to a 5-point severity scale (0 to 4) to provide PGA subscores, which described the overall severity of each clinical sign. The PGA-C was a static assessment; i.e., without regard to a previous assessment. The PGA subscores are then summed and averaged after which the total average was rounded to the nearest whole number to determine the PGA-C score and category. A higher score indicated a higher level of severity. 0 is equal to (=) cleared except for any residual discoloration and 1=almost clear, majority of lesions had individual scores for E+I+S that when summed, averaged, and rounded equaled 1.	Baseline, Week 12
Percentage of Participants Achieving a PGA-C Response of Clear (0) or Almost Clear (1) and ≥2 Grade/Point Improvement From Baseline at Week 8	Clinical signs of plaque psoriasis (E, I, and S) were scored separately according to a 5-point severity scale (0 to 4) to provide PGA subscores, which described the overall severity of each clinical sign. The PGA-C was a static assessment; i.e., without regard to a previous assessment. The PGA subscores are then summed and averaged after which the total average was rounded to the nearest whole number to determine the PGA-C score and category. A higher score indicated a higher level of severity. 0 is equal to (=) cleared except for any residual discoloration and 1=almost clear, majority of lesions had individual scores for E+I+S that when summed, averaged, and rounded equaled 1.	Baseline, Week 8

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants	Clinical signs of plaque psoriasis (E, I, and S) were scored separately according to a 5-point severity	Week 12

Achieving a PGA-C Response of Clear (0) or Almost Clear (1) at Week 12	scale (0 to 4) to provide PGA subscores, which described the overall severity of each clinical sign. The PGA-C was a static assessment; i.e., without regard to a previous assessment. The PGA subscores are then summed and averaged after which the total average was rounded to the nearest whole number to determine the PGA-C score and category. A higher score indicated a higher level of severity. 0 is equal to (=) cleared except for any residual discoloration and 1=almost clear, majority of lesions had individual scores for E+I+S that when summed, averaged, and rounded equaled 1.	
Percentage of Participants Achieving a PGA-C Response of Clear (0) or Almost Clear (1) at Week 8	Clinical signs of plaque psoriasis (E, I, and S) were scored separately according to a 5-point severity scale (0 to 4) to provide PGA subscores, which described the overall severity of each clinical sign. The PGA-C was a static assessment; i.e., without regard to a previous assessment. The PGA subscores are then summed and averaged after which the total average was rounded to the nearest whole number to determine the PGA-C score and category. A higher score indicated a higher level of severity. 0 is equal to (=) cleared except for any residual discoloration and 1=almost clear, majority of lesions had individual scores for E+I+S that when summed, averaged, and rounded equaled 1.	Week 8
Percentage of Participants Achieving a Gestalt Physicians Global Assessment (PGA-G) Response of Clear (0) or Almost Clear (1) and ≥2 Grade/Point Improvement From Baseline at Week 12	Clinical signs of plaque psoriasis (E, I and S) were scored separately according to a 5-point severity scale (0 to 4) to provide PGA subscores, which described the overall severity of each clinical sign. After scoring each of the PGA subscores, a clinical evaluator of psoriasis performed an assessment of the overall severity of psoriasis and assigned a PGA-G score and category. 0=Clear, except for any residual discoloration (post-inflammatory hyperpigmentation and/or hypopigmentation) and 1=almost clear, the psoriasis is not entirely cleared and remaining plaques are light pink (not including post inflammatory hyperpigmentation), and/or have barely palpable elevation and/or have occasional fine scale.	Baseline, Week 12

	The PGA-G was a static assessment; i.e., without regard to a previous assessment.	
Percentage of Participants Achieving a PGA-G Response of Clear (0) or Almost Clear (1) and ≥2 Grade/Point Improvement From Baseline at Week 8	Clinical signs of plaque psoriasis (E, I and S) were scored separately according to a 5-point severity scale (0 to 4) to provide PGA subscores, which described the overall severity of each clinical sign. After scoring each of the PGA subscores, a clinical evaluator of psoriasis performed an assessment of the overall severity of psoriasis and assigned a PGA-G score and category. 0=Clear, except for any residual discoloration (post-inflammatory hyperpigmentation and/or hypopigmentation) and 1=almost clear, the psoriasis is not entirely cleared and remaining plaques are light pink (not including post inflammatory hyperpigmentation), and/or have barely palpable elevation and/or have occasional fine scale. The PGA-G was a static assessment; i.e., without regard to a previous assessment.	Baseline, Week 8
Percent Change From Baseline to Week 12 in Psoriasis Area and Severity Index (PASI)	Combined assessment of lesion severity and area affected into single score. Body was divided into 4 regions: head, arms, trunk, legs. For each region, percent (%) area of skin involved was estimated: 0=0% to 6=90-100%. Severity was estimated by clinical signs: erythema, induration, scaling; scale: 0=none to 4=maximum. Final PASI = sum of severity parameters for each region*area score*weight of region (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4); total possible score range: 0=no disease to 72=maximal disease. The maximum PASI score was <72 since the PASI assessment excluded scalp, palms, finger nails, soles, and toe nails.	Baseline, Week 12
Percent Change From Baseline to Week 8 in PASI	Combined assessment of lesion severity and area affected into single score. Body was divided into 4 regions: head, arms, trunk, legs. For each region, percent area of skin involved was estimated: 0=0% to 6=90-100%. Severity was estimated by clinical signs: erythema, induration, scaling; scale: 0=none to 4=maximum. Final PASI = sum of severity parameters for each region*area score*weight of region (head:	Baseline, Week 8

	0.1, arms: 0.2, body: 0.3, legs: 0.4); total possible score range: 0=no disease to 72=maximal disease. The maximum PASI score was <72 since the PASI assessment excluded scalp, palms, finger nails, soles, and toe nails.	
Percentage of Participants Achieving at Least a 75% Reduction in PASI Response (PASI75), Relative to Baseline at Week 12	Combined assessment of lesion severity and area affected into single score. Body was divided into 4 regions: head, arms, trunk, legs. For each region, percent area of skin involved was estimated: 0=0% to 6=90-100%. Severity was estimated by clinical signs: erythema, induration, scaling; scale: 0=none to 4=maximum. Final PASI = sum of severity parameters for each region*area score*weight of region (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4); total possible score range: 0=no disease to 72=maximal disease. The maximum PASI score was <72 since the PASI assessment excluded scalp, palms, finger nails, soles, and toe nails.	Baseline, Week 12
Percentage of Participants Achieving PASI75, Relative to Baseline at Week 8	Combined assessment of lesion severity and area affected into single score. Body was divided into 4 regions: head, arms, trunk, legs. For each region, percent area of skin involved was estimated: 0=0% to 6=90-100%. Severity was estimated by clinical signs: erythema, induration, scaling; scale: 0=none to 4=maximum. Final PASI = sum of severity parameters for each region*area score*weight of region (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4); total possible score range: 0=no disease to 72=maximal disease. The maximum PASI score was <72 since the PASI assessment excluded scalp, palms, finger nails, soles, and toe nails.	Baseline, Week 8
Percent Change From Baseline to Week 12 in Body Surface Area (BSA) Affected With Psoriasis	Assessment of BSA with psoriasis was performed separately for 4 body regions: head and neck, upper limbs, trunk (including axillae and groin), and lower limbs (including buttocks). The percent surface area with psoriasis was estimated by means of the handprint method, where the full palmar hand of the participant represents approximately 1% of the total BSA. The number of handprints of psoriatic skin in a	Baseline, Week 12

	body region can be used to determine the extent (%) to which a body regions is involved with psoriasis. BSA (%)=the sum of the BSAs of the 4 body regions. BSA assessment excluded head and neck, palms, finger nails, soles and toe nails.	
Percent Change From Baseline to Week 8 in BSA Affected With Psoriasis	Assessment of BSA with psoriasis was performed separately for 4 body regions: head and neck, upper limbs, trunk (including axillae and groin), and lower limbs (including buttocks). The percent surface area with psoriasis was estimated by means of the handprint method, where the full palmar hand of the participant represents approximately 1% of the total BSA. The number of handprints of psoriatic skin in a body region can be used to determine the extent (%) to which a body regions is involved with psoriasis. BSA (%)=the sum of the BSAs of the 4 body regions. BSA assessment excluded head and neck, palms, finger nails, soles and toe nails.	Baseline, Week 8
Change From Baseline to Week 12 in Clinic-Based Itch Severity Item (ISI) Scores	The severity of itch (pruritus) due to psoriasis was assessed using the ISI. Participants were asked to assess their "worst itching due to psoriasis over the past 24 hours" on a numeric rating scale anchored by the terms "no itching" (0) and "worst possible itching" (10) at the ends. Participants completed the ISI assessments at the clinic (i.e., clinic-based).	Baseline, Week 12
Change From Baseline to Week 8 in Clinic-Based ISI Scores	The severity of itch (pruritus) due to psoriasis was assessed using the ISI. Participants were asked to assess their "worst itching due to psoriasis over the past 24 hours" on a numeric rating scale anchored by the terms "no itching" (0) and "worst possible itching" (10) at the ends. Participants completed the ISI assessments at the clinic (i.e., clinic-based).	Baseline, Week 8

Change From Baseline to Week 12 in the Dermatology Life Quality Index (DLQI) Total Score	DLQI is the dermatology-specific quality of life measure used for psoriatic population. The 10-item questionnaire assesses participant health-related quality of life (daily activities, personal relationships, symptoms and feelings, leisure, work and school, and treatment). The DLQI questions are rated by the participant as 0 (not at all/not relevant) to 3 (very much) with a total score range of 0 (best) to 30 (worst); higher scores indicate poor quality of life.	Baseline, Week 12
Change From Baseline to Week 8 in the DLQI Total Score	DLQI is the dermatology-specific quality of life measure used for psoriatic population. The 10-item questionnaire assesses participant health-related quality of life (daily activities, personal relationships, symptoms and feelings, leisure, work and school, and treatment). The DLQI questions are rated by the participant as 0 (not at all/not relevant) to 3 (very much) with a total score range of 0 (best) to 30 (worst); higher scores indicate poor quality of life.	Baseline, Week 8
Percentage of Participants Achieving a Patient s Global Assessment (PtGA) Response of Clear (0) or Almost Clear (1) and ≥2 Grade/Point Improvement From Baseline at Week 12 for Participants With a PtGA Score ≥2 at Baseline	The PtGA asks the participant to evaluate the overall cutaneous disease at that point in time on a single item, 5-point scale (0=clear; 1=almost clear; 2=mild; 3=moderate; 4=severe).	Baseline, Week 12
Percentage of Participants Achieving a PtGA Response of Clear (0) or Almost	The PtGA asks the participant to evaluate the overall cutaneous disease at that point in time on a single item, 5-point scale (0=clear; 1=almost clear; 2=mild; 3=moderate; 4=severe).	Baseline, Week 8

Clear (1) and ≥2 Grade/Point Improvement From Baseline at Week 8 for Participants With a PtGA Score ≥2 at Baseline		

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Pfizer

Collaborators

No information provided

Investigators

- Study Director: Pfizer CT.gov Call Center, Pfizer

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet

specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2013-03-28

First Submitted that Met QC Criteria
2013-04-10

First Posted (Estimated)
2013-04-15

Results Reporting Dates

Results First Submitted
2015-09-15

Results First Submitted that Met QC Criteria
2015-10-26

Results First Posted (Estimated)
2015-11-25

Study Record Updates

Last Update Submitted that met QC Criteria
2015-10-26

Last Update Posted (Estimated)
2015-11-25

Last Verified
2015-10

More Information

Terms related to this study

Keywords Provided by Pfizer

plaque psoriasis
vulgaris
topical treatment
skin diseases

papulosquamous
Tofacitinib
CP-690550
Xeljanz
psoriasis
moderate
severe
itch
nail psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Janus Kinase Inhibitors
Protein Kinase Inhibitors
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action
Tofacitinib

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by Pfizer

To obtain contact information for a study center near you, click here.
(https://trialinfoemail.pfizer.com/pages/landing.aspx?StudyID=A3921082&StudyName=Tofacitinib%20Ointment%20For%20Chronic%20Plaque%20Psoriasis)

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COMPLETED

A Study to Determine the Efficacy and Safety of 122-0551 in Subjects With Plaque Psoriasis

ClinicalTrials.gov ID **NCT01700985**

Sponsor Therapeutics, Inc.

Information provided by Therapeutics, Inc. (Responsible Party)

Last Update Posted 2018 10 25

Study Details Tab

Study Overview

Brief Summary

Feedback

Corticosteroids are one of the mainstays of treatment for subjects with corticosteroid responsive dermatoses such as psoriasis. This study has been designed to determine and compare the efficacy and safety of a formulation of 122 0551 versus the corresponding Vehicle in subjects with stable plaque psoriasis after twice daily dosing for 14 consecutive days.

Official Title

A Double Blind, Randomized, Single Center, Vehicle Controlled, Parallel Group Study to Determine the Efficacy and Safety of 122 0551 in Subjects With Plaque Psoriasis Receiving Two Weeks of Treatment

Conditions

Psoriasis | Plaque Psoriasis

Intervention / Treatment

- Drug: 122 0551
- Drug: Vehicle

Other Study ID Numbers

- 122 0551 203

Study Start

2012 05

Primary Completion (Actual)

2012 09

Study Completion (Actual)

2013 03

Enrollment (Actual)

44

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

California Locations

San Diego, California, United States, 92123
Therapeutics Clinical Research

Click to view interactive map

Texas Locations

Austin, Texas, United States, 78759
DermResearch, Inc.

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Subject has a clinical diagnosis of stable plaque psoriasis
- Subject has an ODS score for the Treatment Area of 3 or 4 at study start

Exclusion Criteria:

- Subject has spontaneously improving or rapidly deteriorating plaque psoriasis.
- Subject has guttate, pustular, erythrodermic or other non plaque forms of psoriasis.
- Subject has used any phototherapy, photo chemotherapy or systemic corticosteroid therapy within 30 days prior to study start
- Subject has used any systemic methotrexate, retinoids, cyclosporine or analogous products within 90 days prior to study start
- Subject has used any systemic biologic therapy for the treatment of psoriasis within 5 half lives of the biologic prior to study start
- Subject had prolonged exposure to natural or artificial sources of ultraviolet radiation within 30 days prior to study start
- Subject has used topical body (excluding the scalp) psoriasis therapy including coal tar, anthralin, steroids, retinoids, vitamin D analogs (e.g., Dovonex®) within 14 days prior to study start
- Subject has used emollients/moisturizers on areas to be treated within four hours prior to clinical evaluation at study start
- Subject is currently using lithium or Plaquenil (hydroxychloroquine)
- Subject is currently using a beta blocking medication (e.g., propranolol) or ACE (e.g., lisinopril) inhibitor at a dose that has not been stabilized
- Subject is pregnant, lactating, or is planning to become pregnant during the study
- Subject is currently enrolled in an investigational drug or device study
- Subject has used an investigational drug or investigational device treatment within 30 days prior to study start
- Subject has been previously enrolled in this study and treated with a test article

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: 122-0551	Drug: 122-0551 • Applied twice daily for two weeks
Placebo Comparator: Vehicle	Drug: Vehicle • Applied twice daily for two weeks

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Change in Overall Disease Severity (ODS) Score	The percentage of subjects with ODS "treatment success" at EOS where EOS is the subject s last completed visit. "Treatment success" is defined as an ODS of 0 or 1. ODS is measured on a 5-point scale: 0 = clear; 1 = almost clear; 2 = mild; 3 = moderate; 4 = severe/very severe.	baseline and Day 15 (End of Study - EOS)

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
ODS "Treatment Success" at Day 8 and Day 15	The percentage of subjects with ODS "treatment success" at Day 8 and Day 15. "Treatment success" is defined as an ODS of 0 or 1. ODS is measured on a 5-point scale: 0 = clear; 1 = almost clear; 2 = mild; 3 = moderate; 4 = severe/very severe.	baseline, Day 8, and Day 15
ODS "Improved" at Day 8 and Day 15	The percentage of subjects rated "improved" with respect to ODS at Days 8 and 15. "Improved" is defined as at least a 2 grade decrease in ODS score relative to baseline. ODS is measured on a 5-point scale: 0 = clear; 1 = almost clear; 2 = mild; 3 = moderate; 4 = severe/very severe.	baseline, Day 8, and Day 15
"Treatment Success" for Clinical Signs and Symptoms of Psoriasis	The percentage of subjects rated "treatment success" for each of the clinical signs and symptoms of psoriasis (scaling, erythema, plaque elevation) at Days 8 and 15. "Treatment success" is defined as a score of 0 or 1 based on a 5-point ordinal scale where 0=clear, 1=almost clear, 2=mild, 3=moderate, and 4=severe.	baseline, Day 8 and Day 15
"Improved" for Clinical Signs and Symptoms of Psoriasis	The percentage of subjects rated "improved" for each of the clinical signs and symptoms of psoriasis (scaling, erythema, plaque elevation, pruritus) at Days 8 and 15. "Improved" is defined as at least a 2 grade decrease in score based on	baseline, Day 8 and Day 15

	a 5-point ordinal scale where 0=clear, 1=almost clear, 2=mild, 3=moderate, and 4=severe.	
Change in % Body Surface Area (BSA) With Psoriasis	Changes in % BSA with active psoriasis in the Treatment Area at Days 8 and 15.	baseline, Day 8 and Day 15

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Therapeutics, Inc.

Collaborators

No information provided

Investigators

- Study Director: Syd Dromgoole, PhD, Therapeutics, Inc.

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2012-09-27

First Submitted that Met QC Criteria
2012-10-02

First Posted (Estimated)
2012-10-04

Results Reporting Dates

Results First Submitted
2018-08-30

Results First Submitted that Met QC Criteria
2018-09-28

Results First Posted
2018-10-25

Study Record Updates

Last Update Submitted that met QC Criteria
2018-09-28

Last Update Posted
2018-10-25

Last Verified
2018-08

More Information

Terms related to this study

Keywords Provided by Therapeutics, Inc.

psoriasis
plaque psoriasis
122 0551
steroid

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

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Record 1 of 1

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COMPLETED

AIN457 Regimen Finding Extension Study in Participants With Moderate to Severe Psoriasis

ClinicalTrials.gov ID **NCT01132612**

Sponsor Novartis Pharmaceuticals

Information provided by Novartis (Novartis Pharmaceuticals) (Responsible Party)

Last Update Posted 2018 01 04

Study Details Tab

Study Overview

Brief Summary

The purpose of this study was to provide long term clinical data for the compound for the treatment of the indication of moderate to severe chronic plaque type psoriasis.

Feedback

Detailed Description

In the Proof of Concept study (CAIN457A2102/ NCT00669916), AIN457 was proven to be efficacious in the treatment of moderate to severe chronic plaque type psoriasis. As a result, a phase IIb regimen finding study had been started (CAIN457A2211/NCT00941031).

The data gathered in this extension study of the core study (CAIN457A2211)was used to expand the safety database of the compound for the treatment of moderate to severe chronic plaque type psoriasis. The participants in the extension study continued to stay on the exact same treatment regimen they were taking when completing the core study. The extension trial was first designed to provide long term safety data of up to 100 weeks of treatment (32 weeks in the core study plus 68 weeks in the extension study (part 1)), and an additional 12 weeks of treatment free follow up for participants who did not continue in the extension study. Amendment 2 provided an additional 156 weeks of treatment (32 weeks in the core study plus 224 weeks in the extension study, equaling 256 weeks of total treatment (part 2)), before participants entered the 12 weeks of treatment free follow up. Protocol Amendment 3 extended the prolongation part of the study by up to 104 additional weeks of treatment (part 3) or until the drug was commercially available in the market of the country of participation, whichever occurred first.

Official Title

A Multicenter Extension Trial of Subcutaneously Administered AIN457 in Participants With Moderate to Severe Chronic Plaque type Psoriasis

Conditions

Plaque type Psoriasis

Intervention / Treatment

- Drug: AIN457
- Drug: Placebo

Other Study ID Numbers

- CAIN457A2211E1
- 2009 017234 51 (EudraCT Number)

Study Start (Actual)

2010 05 11

Primary Completion (Actual)

2016 10 18

Study Completion (Actual)

2016 10 18

Enrollment (Actual)

275

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Alabama Locations

Birmingham, Alabama, United States, 35233
Novartis Investigative Site

Arkansas Locations

Little Rock, Arkansas, United States, 72205
Novartis Investigative Site



Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Key Inclusion Criteria:

- Patients who completed the core study CAIN457A2211. A patient is defined as having completed the core study if he/she completed the study up to and including visit 13 (F4) of the core study
- Patients must be able to understand and communicate with the investigator and comply with the requirement of the study and must given written, signed and dated informed consent before any study assessment is performed.
- Patients must be expected to benefit from the ongoing treatment with AIN457, as assessed by the patient and investigator
- Male patients must consent to practice reliable contraception during the study and for 16 weeks after the last dose of study drug administration Note: Due to new data available from the toxicology studies, the need for male contraception was removed.

Key Exclusion Criteria:

- Patients who experience a second consecutive full relapse at visit 13 (week F4) of the core study CAIN457A2211
- Pregnant or nursing (lactating) women, where pregnancy is defined as the state of a female after conception and until termination of gestation, confirmed by a positive hCG laboratory test (> 5mlU/mL)
- Women of child bearing potential, defined as all women physiologically capable of becoming pregnant, unwilling to use effective contraception during the study and for 16 weeks after stopping treatment.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Fixed-time interval regimen Secukinumab 150 mg subcutaneous (sc) administered at Week 1 (baseline) of the extension study and every 12 weeks thereafter	Drug: AIN457 • AIN457A 150 mg powder for solution Drug: Placebo • Placebo to AIN457A 150 mg powder for solution
Experimental: Treatment at start of relapse regimen Placebo administered at Week 1 (baseline) of the extension study and every 12 weeks thereafter. If relapse, then switch to secukinumab 150 mg sc administered every 4 weeks	Drug: AIN457 • AIN457A 150 mg powder for solution Drug: Placebo • Placebo to AIN457A 150 mg powder for solution
Experimental: Open-label Secukinumab 150 mg sc administered every 4 weeks	Drug: AIN457 • AIN457A 150 mg powder for solution

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With Adverse Events, Serious Adverse Events and Deaths	Safety was assessed by frequency of adverse events including serious adverse events.	up to week 351

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With at Least 50%, 75% or 90% Improvement From Baseline in Psoriasis Area and Severity Index (PASI) and IGA Mod 2009 0 or 1 Response	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). The IGA scale is static, i.e. it referred exclusively to the participant s disease at the time of the assessment, and did not compare with any of the participant s previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate, 4 = severe and 5 = very severe.	Extension weeks: 1, 25, 73 and 301 (too few data points were available to perform analysis at week 301)
Long-term Immunogenicity Assessed by the	Describes the number of participants tested positive for anti-secukinumab antibodies. It refers to the number of participants who had no	up to week 351

Number of Participants Developing Anti Secukinumab Antibodies During the Trial	positive values at baseline but developed them only after start of secukinumab treatment.	

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Novartis Pharmaceuticals

Collaborators

No information provided

Investigators

- Study Director: Novartis Pharmaceuticals, Novartis Pharmaceuticals

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2010-05-19

First Submitted that Met QC Criteria
2010-05-26

First Posted (Estimated)
2010-05-28

Results Reporting Dates

Results First Submitted
2017-10-17

Results First Submitted that Met QC Criteria
2017-11-30

Results First Posted
2017-12-05

Study Record Updates

Last Update Submitted that met QC Criteria
2017-12-08

Last Update Posted
2018-01-04

Last Verified
2017-12

More Information

Terms related to this study

Keywords Provided by Novartis (Novartis Pharmaceuticals)

Chronic plaque type psoriasis
AIN457
dermatology
Moderate to severe chronic plaque type psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full disclaimer (https://clinicaltrials.gov/about site/disclaimer) for details.

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

4 Year Extension Study of Efficacy and Safety of Secukinumab in Patients With Moderate to Severe Chronic Plaque-type Psoriasis

ClinicalTrials.gov ID **NCT01640951**

Sponsor Novartis Pharmaceuticals

Information provided by Novartis (Novartis Pharmaceuticals) (Responsible Party)

Last Update Posted 2018 05 25

Study Details Tab

Study Overview

Brief Summary

CAIN457A2304E1 was an extension study to two phase III studies, CAIN457A2304 and CAIN457A2307 (core studies). This extension study planned to collect up to four years of long term safety, tolerability and efficacy data of secukinumab in both the fixed interval regimen and the

Feedback

retreatment at start of relapse regimen. All subjects who completed the full study treatment period (52 weeks) in the cores studies CAIN457A2304 and CAIN457A2307 were eligible to participate in this extension study. In this extension study, the prefilled syringe (PFS) liquid formulation of secukinumab was used.

Official Title

A Multicenter, Double blind and Open Label, 4 Year Extension Study of Subcutaneous Secukinumab in Prefilled Syringes, Assessing Long term Safety, Tolerability and Efficacy in Subjects With Moderate to Severe Chronic Plaque type Psoriasis Treated With Either a Fixed Dose Regimen or on a Retreatment at Start of Relapse Regimen

Conditions

Moderate to Severe Chronic Plaque Type Psoriasis

Intervention / Treatment

- Drug: AIN457 150 mg
- Drug: AIN457 300 mg
- Drug: Placebo

Other Study ID Numbers

- CAIN457A2304E1
- 2012 000985 39 (EudraCT Number)

Study Start (Actual)

2012 09 16

Primary Completion (Actual)

2017 05 04

Study Completion (Actual)

2017 05 04

Enrollment (Actual)

675

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Secukinumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Secukinumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

California Locations

Fresno, California, United States, 93710
Novartis Investigative Site

Pasadena, California, United States, 91105
Novartis Investigative Site

San Francisco, California, United States, 94118
Novartis Investigative Site

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

1. Subjects must be able to understand and communicate with the investigator and comply with the requirements of the study and must give a written, signed and dated informed consent before any study related activity is performed. Where relevant, a legal representative will also sign the informed consent according to local laws and regulations.
2. Subjects who complete Week 52 of study CAIN457A2304 or complete Week 40 of study CAIN457A2307
3. Subjects expected to benefit from participation in the extension study, as assessed by the subject and investigator

Exclusion Criteria:

1. A protocol deviation in the core studies which according to the investigator will prevent the meaningful analysis of the extension study for the individual subject
2. Ongoing use of prohibited psoriasis or non psoriasis treatments. Time period from last use of prohibited treatments in the core study to first dose of study drug in this extension study.
3. Subjects expected to be exposed to an undue safety risk if participating in the trial
4. Current severe progressive or uncontrolled disease which in the judgment of the investigator renders the subject unsuitable for the trial
5. Plans for administration of live vaccines during the study period
6. Pregnant or nursing (lactating) women, where pregnancy is defined as the state of a female after conception and until the termination of gestation, confirmed by a positive hCG laboratory test (>10 mIU/mL).

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Non Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: AIN457 150 mg - Fixed Interval (FI) 1 s.c. Secukinumab 150 mg Pre-filled seringue (PFS) injection + 1 s.c. Placebo (PBO) Secukinumab PFS injection every 4 weeks	Drug: AIN457 150 mg • (1 injection per dose) and placebo to Secukinumab 150 mg • Other Names: ◦ Secukinumab 150 mg Drug: Placebo
Experimental: AIN457 150 mg - Start of relapse (SoR) Start of relapse: 1 s.c. Secukinumab 150 mg PFS injection + 1 s.c. PBO Secukinumab PFS injection every 4 weeks Otherwise: 2 s.c. PBO Secukinumab PFS injections every 4 weeks	Drug: AIN457 150 mg • (1 injection per dose) and placebo to Secukinumab 150 mg • Other Names: ◦ Secukinumab 150 mg Drug: Placebo
Experimental: AIN457 300 mg - Fixed Interval (FI) 2 s.c. Secukinumab 150 mg PFS injections every 4 weeks	Drug: AIN457 300 mg • Secukinumab 150 mg (2 injections per dose) • Other Names: ◦ Secukinumab 300 mg

Experimental: AIN457 300 mg - Start of Relapse (SoR) Start of relapse: 2 s.c. Secukinumab 150 mg PFS injection every 4 weeks Otherwise: 2 s.c. PBO Secukinumab PFS injections every 4 weeks	Drug: AIN457 300 mg • Secukinumab 150 mg (2 injections per dose) • Other Names: ◦ Secukinumab 300 mg Drug: Placebo
Experimental: AIN457 300 mg - Open Label (OL) Open Label - Secukinumab 300mg every 4 weeks	Drug: AIN457 300 mg • Secukinumab 150 mg (2 injections per dose) • Other Names: ◦ Secukinumab 300 mg

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Long-term Safety and Tolerability of Secukinumab	Analysis of absolute and relative frequencies for treatment emergent Adverse Event (AE), Serious Adverse Event (SAE) and Deaths by primary System Organ Class (SOC)	Week 268

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Percentage of Participants Achieving Psoriasis Area and Severity Index (PASI) Score of 75 at Weeks 52, 104, 156, 208 and 260	PASI: Combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area * area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4)	Week 52, Week 104, Week 156, Week 208, Week 260
Percentage of Participants Achieving Psoriasis Area and Severity Index (PASI) Scores of 50, 90 and 100 Over Time at Weeks 52, 104, 156, 208 and 260	PASI: Combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area * area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4)	Week 52, Week 104, Week 156, Week 208, Week 260
Percent Change From Baseline in Psoriasis Area and Severity Index (PASI) Score at Weeks 52, 104, 156, 208 and 260	PASI: Combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each	Baseline, Week 52, Week 104, Week 156, Week 208, Week 260

	area * area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4)	
Percentage of Participants Achieving Investigator s Global Assessment Modified 2011 (IGA) 2011 Score of 0 or 1 Over Time at Weeks 52, 104, 156, 208 and 260	The IGA mod 2011 is a static scale, i.e., it refers exclusively to the participant s disease state at the time of the assessments and does not attempt a comparison to any of the participant s previous disease states at prior visits. The score ranges from 0 (clear) to 4 (severe). The score 0 is clear, 1 is almost clear, 2 is mild, 3 is moderate, and 4 is severe.	Week 52, Week 104, Week 156, Week 208, Week 260
Percentage Change From Baseline in Dermatology Life Quality Index (DLQI©) Response at Weeks 52, 104, 156, 208 and 260	The DLQI is a quality of life measure used in the psoriatic The 10-item questionnaire has a score range of 0 (best) to 30 (worst) with higher scores indicating poor quality of life. The instrument contains six functional scales (i.e., symptoms and feeling, daily activities, leisure, work and school, personal relationships, treatment). Each item has 4 response categories, ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions	Baseline, Week 52, Week 104, Week 156, Week 208, Week 260
Percentage of Participants With Dermatology Life Quality Index (DLQI©) Response (DLQI 0 or 1) Over Time at Weeks	The DLQI is a quality of life measure used in the psoriatic The 10-item questionnaire has a score range of 0 (best) to 30 (worst) with higher scores indicating poor quality of life. The instrument contains six functional scales (i.e., symptoms and feeling, daily activities, leisure, work and school, personal relationships, treatment). Each item has 4 response categories, ranging from 0 (not at all) to 3 (very much). "Not relevant" is also	Week 52, Week 104, Week 156, Week 208, Week 260

52, 104, 156, 208 and 260	a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions	
EuroQOL 5-Dimension Health Status Questionnaire (EQ-5D©) Score and Percent Change From Baseline at Weeks 52, 104 and 156	ED-5Q: Participant rated questionnaire to assess health related quality of life in terms of a single utility score. Five domains are assessed mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) each with three possible score: 1 indicates no problems, better state of health; 3 indicates worst state of health (example "confined to bed") A visual analog scale (VAS) assesses the health status from 0 (worst possible health state) to 100 (best possible health state)	Baseline, Week 52, Week 104, Week 156
Number of Participants With Treatment Emergent Anti-drug Antibodies (ADA)	The development of anti-secunimubab anti-bodies will decrease a participant s ability to respond to secukinumab treatment.	Week 268
Percentage of Patients With Experiencing a Relapse	Relapse is defined as greater than 50% loss of the maximal PASI improvement from baseline. PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1,	Week 260

	arms: 0.2 body: 0.3 legs: 0.4). A negative mean percentage change indicates improvement.	
Percentage of Patients With Experiencing a Rebound	Rebound of disease is defined as a worsening of PASI of > 125% of the value at baseline (core study), or new pustular, erythrodermic or more inflammatory psoriasis occurring within 8 weeks of stopping therapy (i.e., if this definition was fulfilled at more than 8 weeks after last study treatment administration, this was defined as rebound like event). PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). A negative mean percentage change indicates improvement.	Up to Week 264 (8 weeks post last dose)

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Novartis Pharmaceuticals

Collaborators

No information provided

Investigators

- Study Director: Novartis Pharmaceuticals, Novartis Pharmaceuticals

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2012-07-12

First Submitted that Met QC Criteria
2012-07-13

First Posted (Estimated)
2012-07-16

Results Reporting Dates

Results First Submitted
2018-04-23

Results First Submitted that Met QC Criteria
2018-04-24

Results First Posted
2018-05-25

Study Record Updates

Last Update Submitted that met QC Criteria
2018-04-24

Last Update Posted
2018-05-25

Last Verified
2018-04

More Information

Terms related to this study

Keywords Provided by Novartis (Novartis Pharmaceuticals)

Psoriasis
Plaque
Inflammatory skin disease
Scaly patches
AIN457
Secukinumab
Moderate to Severe Plaque type Psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Immunologic Factors
Physiological Effects of Drugs
Antibodies, Monoclonal

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Undecided

IPD Plan Description

Novartis is committed to sharing with qualified external researchers, access to patient level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.

This trial data availability is according to the criteria and process described on www.clinicalstudydatarequest.com

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

Yes

Studies A U.S. FDA-Regulated Device Product

No

Study Documents

- Study Protocol (https://storage.googleapis.com/ctgov2 large docs/51/NCT01640951/Prot_000.pdf) [PDF, 1.11MB, 2015 04 29]
- Statistical Analysis Plan (https://storage.googleapis.com/ctgov2 large docs/51/NCT01640951/SAP_001.pdf) [PDF, 0.63MB, 2018 04 11]

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

The U.S. government does not review or approve the safety and science of all studies listed on this website.

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ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Study of Adalimumab (HUMIRA®) in Patients With Moderate to Severe Psoriasis (PS) in Spain (PROMISE) (PROMISE)

ClinicalTrials.gov ID **NCT01076192**

Sponsor AbbVie (prior sponsor, Abbott)

Information provided by AbbVie (AbbVie (prior sponsor, Abbott)) (Responsible Party)

Last Update Posted 2016 01 06

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to evaluate the effectiveness and safety of adalimumab as used in routine clinical practice in adult patients with moderate to severe chronic plaque psoriasis in Spain.

Feedback

Detailed Description

PROMISE is a 2 year post authorization study of patients taking adalimumab for Psoriasis. Patients who volunteer to participate will be asked to provide information about their medical history and experiences with adalimumab. No study specific testing will be performed. Patients will be asked to provide data on their experiences with adalimumab approximately every 6 months, or as determined by the study doctor. No drug will be provided as a result of participation in the registry. All treatment decisions are independent of participation in the registry. A total of 547 subjects were enrolled: 532 in the ITT population were analyzed for efficacy (excluding 15 for lack of follow up visits (n=8), non fulfillment of the criteria of moderate to severe PS (n=6) and failure to initiate treatment at the baseline visit (n=1)); 542 were analyzed for safety (excluding 5 due to lack of evaluable safety data).

Official Title

Post authorization, Observational Study to Evaluate the Effectiveness of Adalimumab (HUMIRA®) on Moderate severe Psoriasis Under Conditions of Routine Clinical Practice in Spain.

Conditions

Moderate to severe Chronic Plaque Psoriasis

Intervention / Treatment

Other Study ID Numbers

- P11 067

Study Start

2010 02

Primary Completion (Actual)

2014 09

Study Completion (Actual)

2014 09

Enrollment (Actual)

547

Study Type

Observational

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Adalimumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Adalimumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

No location data

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person s general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Patient 18 years of age or older.
- Patient diagnosed with moderate to severe chronic plaque PS beginning treatment with adalimumab in accordance with the authorized conditions of use.
- Patient gives informed consent in writing.

Exclusion Criteria:

- Patients who cannot be treated in accordance with the local product label
- Patient participating or going to participate in a clinical trial during the study follow up
- Patient with difficulties for adequately reading, understanding and completing a questionnaire

Study Population

Participants with moderate to severe chronic plaque psoriasis

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Sampling Method

Non Probability Sample

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Observational Model : Cohort
Time Perspective: Prospective

Cohorts and Interventions

Group/Cohort
Moderate-to-severe chronic plaque psoriasis Participants with moderate-to-severe chronic plaque psoriasis treated with adalimumab in routine clinical practice

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Mean Change From Baseline in Psoriasis Area and Severity Index (PASI)	PASI is a measurement of the severity of psoriasis. It is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (plaque thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The score ranges from 0 (no psoriasis) to 72 (very severe psoriasis). A lower (and negative) value of change indicates an increase in the severity of the psoriasis, while a positive value indicates an improvement in the severity of the PS. Missing data were imputed using last observation carried forward (LOCF).	Baseline, month 1 and every 3 months the first year and every 6 months up to month 24
Percentage of Participants Achieving a	PASI is a measurement of the severity of psoriasis. It is a composite score based on the degree of effect on body surface area of	Baseline, month 1 and

Reduction in PASI Score of at Least 50% (PASI 50)	psoriasis and the extension of erythema (reddening), induration (plaque thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The score ranges from 0 (no psoriasis) to 72 (very severe psoriasis). PASI 50 response is the percentage of participants who achieved at least a 50% reduction (improvement) from baseline in PASI score. Missing data were imputed using LOCF.	every 3 months the first year and every 6 months up to month 24
Percentage of Participants Achieving a Reduction in PASI Score of at Least 75% (PASI 75)	PASI is a measurement of the severity of psoriasis. It is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (plaque thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The score ranges from 0 (no psoriasis) to 72 (very severe psoriasis). PASI 75 response is the percentage of participants who achieved at least a 75% reduction (improvement) from baseline in PASI score. Missing data were imputed using LOCF.	Baseline, month 1 and every 3 months the first year and every 6 months up to month 24
Percentage of Participants Achieving a Reduction in PASI Score of at Least 90% (PASI 90)	PASI is a measurement of the severity of psoriasis. It is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (plaque thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The score ranges from 0 (no psoriasis) to 72 (very severe psoriasis). PASI 90 response is the percentage of participants who achieved at least a 90% reduction (improvement) from baseline in PASI score. Missing data were imputed using LOCF.	Baseline, month 1 and every 3 months the first year and every 6 months up to month 24

Percentage of Participants Achieving a Reduction in PASI Score of 100% (PASI 100)	PASI is a measurement of the severity of psoriasis. It is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (plaque thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The score ranges from 0 (no psoriasis) to 72 (very severe psoriasis). PASI 100 response is the percentage of participants who achieved a 100% reduction (improvement) from baseline in PASI score. Missing data were imputed using LOCF.	Baseline, month 1 and every 3 months the first year and every 6 months up to month 24
Mean Change From Baseline in Body Surface Area (BSA) Affected	Body Surface Area (BSA) affected or the psoriasis area is determined by the direct calculation of the affected body surface area. This determination was used to evaluate the effectiveness of the treatment during each of the study visits. The change was calculated by deducting the final score from the baseline score. Increased scores correspond to reduction of severity and reduction of BSA. Missing data were imputed using LOCF.	Baseline, month 1 and every 3 months the first year and every 6 months up to month 24
Percentage of Participants With Improvement From Baseline in Physicians Global Assessment (PGA)	The PGA was used to measure participants disease status at the time of assessment. This tool is a horizontal visual analogue 6-point scale measuring the degree of overall psoriatic lesion severity, and scores range from 0 (clear) to 5 (very severe). The percentage of patients who showed an improvement from baseline in their PGA scores is presented. Missing data were imputed using LOCF.	Baseline, month 1 and every 3 months the first year and every 6 months up to month 24

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Mean Change From Baseline in Dermatology Life Quality Index (DLQI)	DLQI is a self-administered Health Related Quality of Life (HRQL) questionnaire specifically for patients with dermatological diseases, adapted and validated in the Spanish population. It consists of 10 items with a Likert response scale for 4 categories and uses a 7 day time reference. It generates a global score that ranges from 0 (better HRQL) to 30 (worse HRQL) points. Change in DLQI was calculated by deducting the final score from the baseline score. Missing data were imputed using LOCF.	Baseline and every 6 months up to month 24
Mean Change From Baseline in EuroQol Quality of Life Questionnaire (EQ-5D) Visual Analogue Scale (VAS)	The EQ-5D VAS records the participant s self-rated health on a scale from 0-100 where increased scores correspond to better HRQL. 0 is the worst imaginable health state and 100 is the best imaginable health state . Change in EQ-5D VAS score was calculated by deducting the final score from the baseline score. Increased scores correspond to better health state. Missing data were imputed using LOCF.	Baseline and every 6 months up to month 24
Mean Change From Baseline in Percentage of Lost Productivity Assessed Using Work Productivity and Activity Impairment Questionnaire: Specific Health	WPAI-SHP is a questionnaire used to evaluate lost productivity. The scores on the WPAI questionnaire are presented as percentages (multiplying the scores by 100), with 0% representing no impact on productivity and 100% representing complete impact on productivity. Change in WPAI-SHP was calculated by deducting the final score from the baseline score. Increased (positive) scores correspond to a reduction in the percentage of lost work productivity. Missing	Baseline and every 6 months up to month 24

Problem (WPAI-SHP)	data were imputed using LOCF. n=the number of participants with data at each time point.	
Number of Participants With Adverse Events of Special Interest (AESIs)	AESIs are adverse events of special interest, including infection, neoplasm, lupus-like, demyelinating disease, serious hepatic and/or haematological event.	From time of informed consent to the final visit after 2 years of observation
Number of Participants With Serious Adverse Events (SAEs)	SAEs are adverse event with any of the following severity criteria: Potentially fatal/endangers life, Hospitalisation or prolonging of hospitalisation, a medically important event that requires medical or surgical intervention to prevent a serious outcome, Disability or persistent incapacitation, death, congenital anomalies and/or miscarriage or abortion. See the Reported Adverse Events Section for more details.	From time of informed consent to the final visit after 2 years of observation

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

AbbVie (prior sponsor, Abbott)

Collaborators

- IMS Health

Investigators

- Study Director: Cristina Sancho Sanchez, PharmD, Abbvie Farmaceutica, S.L.U. Spain

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

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Study Registration Dates

First Submitted
2010-02-24

First Submitted that Met QC Criteria
2010-02-24

First Posted (Estimated)
2010-02-26

Results Reporting Dates

Results First Submitted
2015-09-25

Results First Submitted that Met QC Criteria
2015-12-01

Results First Posted (Estimated)
2016-01-06

Study Record Updates

Last Update Submitted that met QC Criteria

2015-12-01

Last Update Posted (Estimated)

2016-01-06

Last Verified

2015-12

More Information

Terms related to this study

Keywords Provided by AbbVie (AbbVie (prior sponsor, Abbott))

Moderate Psoriasis
Psoriasis
Severe Psoriasis
Adalimumab
Effectiveness
Safety
Clinical practice

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by AbbVie (AbbVie (prior sponsor, Abbott))

Related Info (http://rxabbvie.com)

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Evaluation of Etanercept in Patients With Plaque Psoriasis After Stopping Ciclosporin Therapy

ClinicalTrials.gov ID **NCT00581555**

Sponsor Pfizer

Information provided by Pfizer (Responsible Party)

Last Update Posted 2012 04 23

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to evaluate the use of etanercept as a replacement therapy for ciclosporin in patients with plaque psoriasis.

Feedback

Detailed Description

The purpose of this study is to evaluate the efficacy and safety of etanercept as a replacement therapy for ciclosporin in patients with moderate to severe plaque psoriasis who have achieved an adequate response with ciclosporin.

Official Title

A Randomized Pilot Study Evaluating the Efficacy and Safety of Etanercept in Patients With Moderate to Severe Plaque Psoriasis After Cessation of Ciclosporin Therapy

Conditions

Psoriasis

Intervention / Treatment

- Drug: Etanercept
- Other: Placebo

Other Study ID Numbers

- 0881A6 410

Study Start

2007 10

Primary Completion (Actual)

2009 11

Study Completion (Actual)

2009 11

Enrollment (Actual)

120

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Cyclosporine (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Cyclosporine) Etanercept (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Etanercept)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

No location data

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person s general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Between age 18 and 70 years
- Active and stable plaque psoriasis with a BSA≥10 or PASI≥10.

Exclusion Criteria:

- Evidence of skin conditions other than psoriasis
- Psoralen plus psoralen + ultraviolet A (PUVA), ciclosporin, acitretin, alefacept, anakinra, or any other systemic anti psoriasis therapy or disease modifying antirheumatic drugs (DMARD) with 28 days of screening
- ultraviolet B (UVB) therapy, topical steroids, topical Vitamin A or D analog preparations, or anthralin
- Prior exposure to any TNF inhibitor. Prior exposure to efalizumab
- Corticosteroid dose of prednisone >10 mg/day
- Serious infection
- Receipt of any live vaccine
- Abnormal hematology or chemistry
- Body mass index (BMI) > 38
- Pregnancy or Breastfeeding
- Significant concurrent medical conditions

Ages Eligible for Study

18 Years to 70 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: etanercept Participants were administered a 50 mg dose of etanercept subcutaneously once a week after an initial course of ciclosporin.	Drug: Etanercept • Etanercept 50 mg QW initiated during taper of ciclosporin • Other Names: ◦ Enbrel
Placebo Comparator: placebo Participants were administered placebo subcutaneously once a week after an initial course of ciclosporin.	Other: Placebo • Randomized to placebo during taper of ciclosporin

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Randomization in PASI Score to Week 24	PASI score: range: 0 (none) to 72 (maximum). Body was divided into head, upper extremities, trunk and	Randomization to Week 24.

(Week 18 of Etanercept Monotherapy/Placebo)	lower extremities; each area score was combined for final PASI. For each section, percent area of skin involved was estimated: 0 (0%) to 6 (90 - 100%), and severity was estimated by clinical signs: (erythema, induration, and desquamation); scale: 0 (none) to 4 (maximum). Final PASI= sum of severity parameters for each section times area score times weight of section (head: 0.1, upper extremities: 0.2, trunk: 0.3, lower extremities: 0.4). Change = PASI at Week 24 - PASI at baseline.	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
PASI Area Under the Curve (AUC) Between Randomization and Week 24	PASI AUC = Area under the curve from randomization (Week 6) to Week 24.	Randomization to Week 24.
Change From Randomization in PGA Score to Week 24	PGA score is based on dermatologist s assessment of disease averaged over all lesions. Overall lesions were graded for individual scores of induration, erythema, and scaling; range: 0 (no evidence) to 5 (severe). The sum of the 3 scores was divided by 3 to obtain a final PGA score. Higher scores indicate greater severity of disease. Change = PGA at Week 24 - PGA at baseline.	Randomization to Week 24.
Relapse (Loss of 50%	Relapse was defined as the loss of 50% improvement in PASI.	Randomization to Week 24.

Improvement in PASI) During the 24 Weeks After Randomization		
Probability of Being Relapse Free During the 24 Weeks After Randomization	Relapse was defined as loss of 50% improvement in PASI. The time to relapse was estimated using a Kaplan-Meier analysis.	Randomization to Week 24.
Percent (%) Change of PASI Score From Randomization to Week 24	Percent improvement in PASI score was calculated from Week 6 to Week 24.	Randomization to Week 24.
Change From Randomization in DLQI to Week 24	DLQI is the dermatology-specific quality of life measure used for psoriatic population. The 10-item questionnaire has a score range of 0 to 30 with higher scores indicating poor quality of life. An estimate of the minimal clinically important difference of the DLQI total score is a 5 point improvement. Total score range: 0 (best) to 30 (worst).	Randomization to Week 24.
DLQI at Each Visit From Baseline	DLQI is the dermatology-specific quality of life measure used for psoriatic population. The 10 item questionnaire has a score range of 0 to 30 with higher scores indicating poor quality of life. An estimate of the minimal clinically important difference of the DLQI total score is a 5 point improvement. Total score range: 0 (best) to 30 (worst).	Baseline to Week 24.

Percentage of Rebound Effects	Rebound effects was defined as worsening of psoriasis to 125% of the baseline PASI or appearance of psoriasis variants such as erythrodermic or pustular psoriasis within 12 weeks of discontinuation of therapy.	Baseline to Week 24.

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Pfizer

Collaborators

No information provided

Investigators

- Study Director: Medical Monitor, Wyeth is now a wholly owned subsidiary of Pfizer

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

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Study Registration Dates

First Submitted
2007-12-21

First Submitted that Met QC Criteria
2007-12-21

First Posted (Estimated)
2007-12-27

Results Reporting Dates

Results First Submitted
2010-11-17

Results First Submitted that Met QC Criteria
2012-03-28

Results First Posted (Estimated)
2012-04-23

Study Record Updates

Last Update Submitted that met QC Criteria
2012-03-28

Last Update Posted (Estimated)
2012-04-23

Last Verified
2012-03

More Information

Terms related to this study

Keywords Provided by Pfizer

Psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Anti Inflammatory Agents, Non Steroidal
Analgesics, Non Narcotic
Analgesics
Sensory System Agents
Peripheral Nervous System Agents
Physiological Effects of Drugs
Anti Inflammatory Agents
Antirheumatic Agents
Gastrointestinal Agents
Immunosuppressive Agents
Immunologic Factors
Etanercept

Study Documents

No study documents available

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Record 1 of 1

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COMPLETED

Brodalumab Drug-Drug Interaction (DDI) and Intensive Pharmacodynamic (PK) Study in Psoriasis Subjects

ClinicalTrials.gov ID **NCT01937260**

Sponsor Bausch Health Americas, Inc.

Information provided by Bausch Health Americas, Inc. (Responsible Party)

Last Update Posted 2017 04 10

Study Details Tab

Study Overview

Brief Summary

Feedback

This is a phase 1, multi center, open label, drug drug interaction (DDI) and PK study in subjects with moderate to severe plaque psoriasis. It is designed to evaluate the effect of brodalumab on midazolam PK in addition to assessing single dose PK of brodalumab in subjects with moderate to severe plaque psoriasis.

Detailed Description

Approximately 30 subjects will be enrolled into two groups. Group 1 consists of 20 subjects and will receive 2 oral doses of midazolam and a single subcutaneous (SC) dose of brodalumab. Group 2 consists of 10 subjects and will receive a single SC dose of brodalumab.

Official Title

An Open label Study to Evaluate the Effect of Brodalumab on the Pharmacokinetics of Midazolam and Assess Single Dose Brodalumab Pharmacokinetics in Subjects With Moderate to Severe Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Brodalumab

Other Study ID Numbers

- 20110184

Study Start

2013 09

Primary Completion (Actual)

2014 07

Study Completion (Actual)

2014 12

Enrollment (Actual)

31

Study Type

Interventional

Phase

Phase 1

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Brodalumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Brodalumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

California Locations

Anaheim, California, United States, 92801
Research Site

Irvine, California, United States, 92697
Research Site

Florida Locations

Ocala, Florida, United States, 34471
Research Site



Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Subject has had stable moderate to severe plaque psoriasis for at least 6 months
- body mass index (BMI) between ≥ 18.0 and ≤ 38.0 kg/m2
- body weight between ≥ 50 and ≤ 130 kg
- no known history of active tuberculosis

Exclusion Criteria:

- Female subjects who are lactating/breastfeeding
- History or evidence of clinically significant disorder, condition or disease that, in the opinion of the investigator or Amgen physician would pose a risk to subject safety or interfere with the study evaluation, procedures or completion.

Ages Eligible for Study

18 Years to 75 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Other
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Brodalumab 140mg SC open label, all subjects receive brodulamab	Drug: Brodalumab • Group 1 consists of 20 subjects and will receive 2 oral doses of midazolam and a single SC dose of brodalumab. Group 2 consists of 10 subjects and will receive a single SC dose of brodalumab. • Other Names: ◦ AMG 827
Experimental: Midazolam (MDZ) 2mg oral, Brodalumab 210mg SC MDZ 2mg oral (Day 1 and Day 9), Brodalumab 210mg SC (Day 2)	Drug: Brodalumab • Group 1 consists of 20 subjects and will receive 2 oral doses of midazolam and a single SC dose of brodalumab. Group 2 consists of 10 subjects and will receive a single SC dose of brodalumab. • Other Names: ◦ AMG 827

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Maximum Observed Concentration of Midazolam After a Single	Midazolam pharmacokinetic parameter estimates after single oral dose of Midazolam 2 mg on Day 1 and Day 9 and a single administration of Brodalumab 210 mg on Day 2 with PK sampling collected on Day 30	Day 1 to day 9

Dose of Brodalumab		
The Area Under Drug Concentration Time Curve From Zero to Infinity (AUCinf)	Midazolam pharmacokinetic parameter estimates after single oral dose of Midazolam 2 mg on Day 1 and Day 9 and a single administration of Brodalumab 210 mg on Day 2 with PK sampling collected on day 30	Day 1 to Day 9
The Area Under the Drug-concentration Curve of Midazolam After a Single Dose of Brodalumab From Zero Tot he Last Time of Quantifiable Concentration	Midazolam pharmacokinetic parameter estimates after single oral dose of Midazolam 2 mg on Day 1 and Day 9 and a single administration of Brodalumab 210 mg on Day 2	Day 1 to Day 9

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Bausch Health Americas, Inc.

Collaborators

No information provided

Investigators

- Study Director: MD, Amgen

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

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Study Registration Dates

First Submitted
2013-07-15

First Submitted that Met QC Criteria
2013-09-04

First Posted (Estimated)
2013-09-09

Results Reporting Dates

Results First Submitted
2016-11-08

Results First Submitted that Met QC Criteria
2017-04-07

Results First Posted
2017-04-10

Study Record Updates

Last Update Submitted that met QC Criteria
2017-04-07

Last Update Posted
2017-04-10

Last Verified
2017-04

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Dermatologic Agents
Brodalumab

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by Bausch Health Americas, Inc.

AmgenTrials clinical trials website (http://www.amgentrials.com)

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COMPLETED

Study to Demonstrate Equivalent Efficacy and to Compare Safety of Biosimilar Adalimumab (GP2017) and Humira (ADACCESS)

ClinicalTrials.gov ID **NCT02016105**

Sponsor Sandoz

Information provided by Sandoz (Responsible Party)

Last Update Posted 2017 05 30

Study Details Tab

Study Overview

Brief Summary

The aim of the study is to demonstrate equivalent efficacy and similarity in the safety profile of GP2017 and Humira® in patients with moderate to severe chronic plaque type psoriasis.

Feedback

Detailed Description

The aim of this study (Treatment Period 1) was to demonstrate equivalent efficacy, primarily based on the PASI75 response rate at Week 16, and similar safety of the proposed biosimilar GP2017 and Humira in patients with moderate to severe chronic plaque type psoriasis at the end of Treatment Period 1, after 17 weeks of study treatment.

The subsequent Treatment Period 2 (Week 17 to Week 35) and the Extension Period (Week 35 to Week 51) were performed to evaluate long term effects, including immunogenicity (i.e. ADAs), and the effects of repeated switching between GP2017 and Humira.

Official Title

A Randomized, Double blind, Multicenter Study to Demonstrate Equivalent Efficacy and to Compare Safety and Immunogenicity of a Biosimilar Adalimumab (GP2017) and Humira® in Patients With Moderate to Severe Chronic Plaque type Psoriasis

Conditions

Plaque Type Psoriasis

Intervention / Treatment

- Drug: GP2017 Adalimumab
- Drug: Humira ® Adalimumab

Other Study ID Numbers

- GP17 301
- 2013 000747 11 (EudraCT Number)

Study Start

2013 12

Primary Completion (Actual)

2015 07

Study Completion (Actual)

2016 02

Enrollment (Actual)

465

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Adalimumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Adalimumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Alabama Locations

Birmingham, Alabama, United States
Total Skin & Beauty Dermatology Center

Arizona Locations

Phoenix, Arizona, United States, 85032
Alliance Dermatology & MOHS Center, PC

Arkansas Locations

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Men or women at least 18 years of age at time of screening
- Chronic plaque type psoriasis diagnosed for at least 6 months before randomization
- Moderate to severe psoriasis as defined at baseline by:
  - PASI score of 12 or greater
  - Investigator´s Global Assessment score of 3 or greater (based on a scale of 0 4) and,
  - Body Surface Area affected by plaque type psoriasis of 10% or greater
- Chronic plaque type psoriasis patients who have previously received phototherapy or systemic psoriasis therapy at least once or who are candidates for such therapies in the opinion of the investigator.

Exclusion Criteria:

- Forms of psoriasis other than chronic plaque type
- Drug induced psoriasis
- Ongoing use of prohibited psoriasis treatments
- Previous exposure to adalimumab
- Active ongoing inflammatory diseases other than psoriasis that might confound the evaluation of the benefit of treatment with adalimumab

Other In /Exclusion criteria may apply

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: GP2017 Adalimumab Study arm with intervention being studied in the protocol. Adalimumab Solution for subcutaneous injection with an initial dose of 80 mg s.c. in Week 0, followed by 40 mg s.c. eow, starting at Week 1 and ending at Week 51.	Drug: GP2017 Adalimumab
Active Comparator: Humira ® Adalimumab Humira® Adalimumab as a subcutaneous injection with an initial dose of 80 mg s.c. in Week 0, followed by 40 mg s.c. eow, starting at Week 1 and ending at Week 51.	Drug: Humira ® Adalimumab

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame

PASI 75 Response Rate at Week 16 - GP2017 Adalimumab vs Humira ® Adalimumab	The primary variable was the PASI75 response rate at Week 16, defined as the proportion of patients achieving a reduction of 75% or more of the PASI score at Week 16 compared with baseline.	At Week 16 only

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Mean Percent Change From Baseline in PASI Score up to Week 16 (MMRM)	The key secondary efficacy variable was the percentage change from baseline in PASI score at each visit up to Week 16.	Baseline to Week 16
Mean ATE of Percent Change From Baseline in PASI Score up to Week 16 (ANCOVA)	The key secondary efficacy variable was the average treatment effect (ATE) which is the weighted average of % change from baseline in PASI scores between Week 1 and Week 16 (weights based on the time interval between two consecutive visits).	Baseline to Week 16
PASI 50, PASI 75, PASI 90 and PASI 100 Response Rates	Proportion of patients achieving PASI 50, 75, 90 and 100 at Week 17 (end of Treatment Period 1)	At Week 17 only
PASI 50, PASI75, PASI 90 and PASI100 Response Rates	Proportion of Patients Achieving PASI 50, 75, 90 and 100 at Week 35 (end of Treatment Period 2)	At Week 35 only

PASI 50, PASI75, PASI 90 and PASI100 Response Rates	Proportion of Patients Achieving PASI 50, 75, 90 and 100 at Week 51 (Entire Study)	At Week 51 only
IGA Response Rate	Proportion of patients achieving a score of 0 ("clear") or 1 ("almost clear") or improved by at least 2 points of the IGA scale compared to baseline at Week 17.	At Week 17 only
IGA Response Rate	Proportion of patients achieving a score of 0 ("clear") or 1 ("almost clear") or improved by at least 2 points of the IGA scale compared to baseline at Week 51	At Week 35 only
IGA Response Rate	Proportion of patients achieving a score of 0 ("clear") or 1 ("almost clear") or improved by at least 2 points of the IGA scale compared to baseline at Week 51	At Week 51 only
DLQI	Proportion of patients reporting a DLQI of 0 or 1 (no effect at all on patient s life)	At Week 17 only
DLQI	Proportion of patients reporting a DLQI of 0 or 1 (no effect at all on patient s life)	At Week 35 only
DLQI	Proportion of patients reporting a DLQI of 0 or 1 (no effect at all on patient s life)	At Week 51 only
ADA Formation Against GP2017 Adalimumab and Humira® Adalimumab From Randomization Until Week 17	Proportion of patients with at least one confirmed positive anti-drug antibodies (ADA) response to adalimumab from Randomization to Week 17. Patients with ADA positive results at baseline were excluded from subsequent results.	At Week 17 only

ADA Formation Against GP2017 Adalimumab and Humira® Adalimumab From Randomization Until Week 51	Proportion of patients with at least one confirmed positive anti-drug antibodies (ADA) response to adalimumab from Randomization to Week 51. Patients with ADA positive results at baseline were excluded from subsequent results.	At Week 51 only

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Sandoz

Collaborators

- Hexal AG

Investigators

No information provided

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2013-12-14

First Submitted that Met QC Criteria
2013-12-14

First Posted (Estimated)
2013-12-19

Results Reporting Dates

Results First Submitted
2017-02-22

Results First Submitted that Met QC Criteria
2017-02-22

Results First Posted
2017-04-07

Study Record Updates

Last Update Submitted that met QC Criteria
2017-04-24

Last Update Posted
2017-05-30

Last Verified
2017-04

More Information

Terms related to this study

Keywords Provided by Sandoz

plaque type psoriasis
equivalent efficacy
safety and immunogenicity
GP2017
Humira®

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Tumor Necrosis Factor Inhibitors
Anti Inflammatory Agents
Antirheumatic Agents
Adalimumab

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Undecided

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

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Record 1 of 1

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COMPLETED

Five-Year Observation of Remicade Treatment for Plaque Psoriasis in Austria (Study P04900)

ClinicalTrials.gov ID **NCT00725452**

Sponsor Merck Sharp & Dohme LLC

Information provided by Merck Sharp & Dohme LLC (Responsible Party)

Last Update Posted 2015 07 28

Study Details Tab

Study Overview

Brief Summary

Prospective, open label , 1 arm, multicenter observational study to determine the dose and interval of Infliximab infusions for subjects with plaque psoriasis.

Feedback

Detailed Description

This study population was chosen from a non probability sample.

Official Title

Real Life Treatment Regimen of Remicade (Infliximab) in Austria, Monitored Over 5 Years in Plaque Psoriasis Therapy

Conditions

Psoriasis

Intervention / Treatment

- Biological: Infliximab

Other Study ID Numbers

- P04900

Study Start

2006 10

Primary Completion (Actual)

2010 06

Study Completion (Actual)

2010 06

Enrollment (Actual)

26

Study Type

Observational

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Infliximab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Infliximab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

No location data

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person s general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- According to the European Summary of Product Characteristics (SPC): Adult subjects with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to other systematic therapy including cyclosporine, methotrexate, or Psoralen ultraviolet A light (PUVA).

Exclusion Criteria:

- According to the European SPC:
  - Subjects with tuberculosis or other severe infections such as sepsis, abscesses, and opportunistic infections.
  - Subjects with moderate to severe heart failure (New York Heart Association (NYHA) class III/IV).
  - Subjects with a history of hypersensitivity to Infliximab or to other murine proteins or to any of the excipients.
  - Subjects with elevated liver enzymes (>5 upper limit of normal (ULN)).

Study Population

Adult subjects with moderate to severe plaque psoriasis will receive Infliximab induction therapy in specialized centers.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Sampling Method

Non Probability Sample

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Observational Model : Cohort
Time Perspective: Prospective

Cohorts and Interventions

Group/Cohort	Intervention/Treatment
Infliximab Subjects with plaque psoriasis will receive Infliximab initial induction therapy consisting of 3 Infliximab infusions at weeks 0, 2, and 6 given in specialized centers. A maximum of 6 maintenance infusions will be given in doses and intervals due to the discretion of the physicians.	Biological: Infliximab • Infliximab initial induction therapy consisting of 3 Infliximab infusions at weeks 0, 2, and 6 given in specialized centers. A maximum of 6 maintenance infusions will be given in doses and intervals due to the discretion of the physicians. • Other Names: ◦ Remicade ◦ SCH 215596

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Therapies That Were Applied as Induction,	The types of therapies were assessed according to the following criteria:	Maximum 2 years

Maintenance, or Episodic Therapies After One Infusion of Infliximab	Induction therapy: first infusion given at Week 0 (Baseline). Second infusion given at Week 2 (+/- 7 days). Third infusion given at Week 6 (+/- 7 days). Maintenance therapy: given in approximately 8-week (56-day) intervals (time window +4 weeks to -2 weeks). One infusion given out of the time window was accepted to be classified as maintenance therapy, if the remaining infusions were given within the time window (8 weeks, +4 to -2 weeks). Episodic Therapy: given out of time frame (> 12 weeks).	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Mean Time Interval Between Infliximab Infusions During Maintenance Treatment Following Induction Therapy		Maximum 2 years
Median Time Interval Between Infliximab Infusions During Maintenance Treatment Following		Maximum 2 years

Induction Therapy		
Mean Dose of Infliximab		Maximum 2 years
Median Dose of Infliximab		Maximum 2 years
Mean Percent Change From Baseline in Body Surface Area (BSA) Involved With Psoriasis After Treatment With Infliximab	BSA estimation was determined using the participant s handprint (palmar surface of palms plus five digits). The number of handprints that covered the affected skin area was counted. One handprint was approximately equivalent to 1 percent of the BSA; therefore, BSA was calculated in percentages. The change from Baseline in BSA was calculated by subtracting Baseline from infusion 9.	Baseline and Infusion 9

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Merck Sharp & Dohme LLC

Collaborators

- Centocor, Inc.

Investigators

No information provided

Publications

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General Publications

No publications available

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Study Record Dates

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Study Registration Dates

First Submitted
2008-07-25

First Submitted that Met QC Criteria
2008-07-25

First Posted (Estimated)
2008-07-30

Results Reporting Dates

Results First Submitted
2011-06-13

Results First Submitted that Met QC Criteria
2011-08-02

Results First Posted (Estimated)
2011-09-02

Study Record Updates

Last Update Submitted that met QC Criteria
2015-07-15

Last Update Posted (Estimated)
2015-07-28

Last Verified

2015-07

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Tumor Necrosis Factor Inhibitors
Anti Inflammatory Agents
Dermatologic Agents
Gastrointestinal Agents
Antirheumatic Agents
Infliximab

Study Documents

No study documents available

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COMPLETED

Effectiveness of Adalimumab in Moderate to Severe Plaque Psoriasis Patients With Distinct Co-morbidities (EPIC)

ClinicalTrials.gov ID **NCT01401452**

Sponsor AbbVie (prior sponsor, Abbott)

Information provided by AbbVie (AbbVie (prior sponsor, Abbott)) (Responsible Party)

Last Update Posted 2017 10 04

Study Details Tab

Study Overview

Brief Summary

This multicenter, post marketing observational study (PMOS) was designed to evaluate the effectiveness of adalimumab over a period of 9 months as determined by the Psoriasis Area and Severity Index (PASI) in participants with moderate to severe plaque psoriasis with distinct co

Feedback

morbidities. Secondary objectives of this study were to measure changes in psychological health via the Dermatology Life Quality Index (DLQI); changes in comorbidities with respect to gender; changes in quality of life using the Short Form Health Survey (SF 36); and evaluation of Minimal Clinically Important Differences (MCID).

Detailed Description

Male or female participants ages 18 years of age and older for whom the treating physician had recently prescribed adalimumab were included in this study. Adalimumab was prescribed in accordance with the terms of the local marketing authorization with regards to dose, population, and indication. There were 5 planned visits during the study: baseline (Visit 1), 1 month (Visit 2), 3 months (Visit 3), 6 months (Visit 4), and 9 months (Visit 5).

Official Title

Effectiveness of Adalimumab in Moderate to Severe Plaque Psoriasis Patients With Distinct Co morbidities

Conditions

Moderate to Severe Plaque Psoriasis

Intervention / Treatment

Other Study ID Numbers

- P12 770

Study Start

2011 08

Primary Completion (Actual)

2016 05

Study Completion (Actual)

2016 05

Enrollment (Actual)

246

Study Type

Observational

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

No location data

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

Participants for whom adalimumab therapy is indicated and has been prescribed according to the product label and who meet the following criteria:

- Participant age ≥ 18 years
- Participants with moderate to severe plaque psoriasis participants who have at last one co morbid disease and/or symptom such as hypertension, psoriatic arthritis confirmed by a rheumatologist or other appropriate specialist, obesity, diabetes, metabolic syndrome or depression (diagnosed by a medical specialist for psychology, neurology, or psychiatry)
- Adalimumab naïve participants with moderate to severe plaque psoriasis after unsatisfactory response, non tolerability, or contraindication of systemic therapies such as ciclosporin, methotrexate or PUVA (psoralen + UVA) or after biological disease modifying anti rheumatic drugs (bDMARDs) failure (e.g.: infliximab, etanercept or ustekinumab)
- Participants of each country must fulfill any local treatment recommendation for use of bDMARD in psoriasis in their respective country. For Austria: participants must fulfill Austrian Treatment Recommendations for use of bDMARD in psoriasis (Chest X ray and IGRA* interferon gamma release assay or PPD skin test negative for tuberculosis)
- Participant is willing to give informed consent to anonymous data collection and their forwarding to AbbVie as well as to informed consent if required in different countries.
- Participant must be able and willing to self administer adalimumab injections or have a qualified person available to administer Humira® syringe or Humira® Pen injections

Exclusion Criteria:

The following participants will not be included in this observational study:

- Participants who meet contraindications as outlined in the latest version of the Humira syringe® Summary of Product Characteristics (SPC) and Humira Pen® SPC
- Participants participating in another study program or clinical trial
- Participants who have been treated with Humira® before

Study Population

Hospital, Dermatology

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Sampling Method

Non Probability Sample

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Observational Model : Cohort
Time Perspective: Prospective

Cohorts and Interventions

Group/Cohort
Participants with psoriasis and at least one co-morbid disease Participants with moderate to severe plaque psoriasis with at least one co-morbid disease and/or symptom such as hypertension, psoriatic arthritis confirmed by a rheumatologist or other appropriate specialist, obesity, diabetes, metabolic syndrome or depression

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Achieving a Psoriasis Area	The percentage of participants with a ≥ 75% reduction (improvement) in the Psoriasis Area and Severity Index (PASI) score from baseline was calculated. PASI is a combination of the	Baseline, Months 1, 3, 6, and 9

and Severity Index 75 (PASI 75) Response at Months 1, 3, 6, and 9	intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and desquamation (scaling) on a scale from no symptoms (0), slight (1), moderate (2), marked (3) or very marked (4), together with the percentage of the area affected, rated on a scale from 0 to 6. PASI scoring is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 to 72. The higher the total score, the more severe the disease.	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Mean Dermatology Life Quality Index (DLQI) Scores	The DLQI questionnaire asks participants to evaluate the degree that psoriasis has affected their quality of life in the last week, and includes the following parameters: symptoms and feelings, daily activities, leisure activities, work or school activities, personal relationships and treatment- related feelings. Participants respond to 10 questions on a scale from 0 (not at all) to 3 (very much); the range of the total score is 0 to 30. A score of 21 to 30 means that psoriasis has an extremely large effect on the participant s life whereas 0-1 means that the disease has no effect at all.	Baseline, Months 1, 3, 6, and 9
Percentage of Participants Achieving a Psoriasis Area and Severity Index 50 (PASI 50) Response at Months 1, 3, 6, and 9	The percentage of participants with a ≥ 50% reduction (improvement) in the Psoriasis Area and Severity Index (PASI) score from baseline was calculated. PASI is a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and desquamation (scaling) on a scale from no symptoms (0), slight (1), moderate (2), marked (3) or very marked (4), together with the percentage of the area affected, rated on a scale from 0 to 6. PASI scoring is performed at four	Baseline, Months 1, 3, 6, and 9

	body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 to 72. The higher the total score, the more severe the disease.	
Percentage of Participants Achieving a Psoriasis Area and Severity Index 90 (PASI 90) Response at Months 1, 3, 6, and 9	The percentage of participants with a ≥ 90% reduction (improvement) in the Psoriasis Area and Severity Index (PASI) score from baseline was calculated. PASI is a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and desquamation (scaling) on a scale from no symptoms (0), slight (1), moderate (2), marked (3) or very marked (4), together with the percentage of the area affected, rated on a scale from 0 to 6. PASI scoring is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 to 72. The higher the total score, the more severe the disease.	Baseline, Months 1, 3, 6, and 9
Percentage of Participants Achieving a Psoriasis Area and Severity Index 100 (PASI 100) Response at Months 1, 3, 6, and 9	The percentage of participants with a ≥ 100% reduction (improvement) in the Psoriasis Area and Severity Index (PASI) score from baseline was calculated. PASI is a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and desquamation (scaling) on a scale from no symptoms (0), slight (1), moderate (2), marked (3) or very marked (4), together with the percentage of the area affected, rated on a scale from 0 to 6. PASI scoring is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 to 72. The higher the total score, the more severe the disease.	Baseline, Months 1, 3, 6, and 9
Mean Health Assessment Questionnaire Short Form 36 (SF-36) Physical Component	The Health Assessment Questionnaire Short Form 36 (SF-36) determines participants overall quality of life by assessing 1) limitations in physical functioning due to health problems; 2) limitations in usual role because of physical health problems; 3) bodily pain; 4) general health	Baseline, Months 1, 3, 6, and 9

Summary (PCS) Scores at 1, 3, 6, and 9 Months	perceptions; 5) vitality; 6) limitations in social functioning because of physical or emotional problems; 7) limitations in usual role due to emotional problems; and 8) general mental health. Items 1-4 primarily contribute to the physical component summary score (PCS) of the SF-36. Items 5-8 primarily contribute to the mental component summary score (MCS) of the SF-36. Scores on each item are summed and averaged (range = 0 "worst"-100 "best"). Increases from baseline indicate improvement. Assessments were conducted at baseline, 1 month, 6 months, and 9 months.	
Mean Health Assessment Questionnaire Short Form 36 (SF-36) Mental Component Summary (MCS) Scores at 1, 3, 6, and 9 Months	The Health Assessment Questionnaire Short Form 36 (SF-36) determines participants overall quality of life by assessing 1) limitations in physical functioning due to health problems; 2) limitations in usual role because of physical health problems; 3) bodily pain; 4) general health perceptions; 5) vitality; 6) limitations in social functioning because of physical or emotional problems; 7) limitations in usual role due to emotional problems; and 8) general mental health. Items 1-4 primarily contribute to the physical component summary score (PCS) of the SF-36. Items 5-8 primarily contribute to the mental component summary score (MCS) of the SF-36. Scores on each item are summed and averaged (range = 0 "worst"-100 "best"). Increases from baseline indicate improvement. Assessments were conducted at baseline, 1 month, 6 months, and 9 months.	Baseline, Months 1, 3, 6, and 9
Percentage of Participants Achieving Minimal Clinically Important	The Health Assessment Questionnaire Short Form 36 (SF-36) determines participants overall quality of life by assessing 1) limitations in physical functioning due to health problems; 2) limitations in usual role because of physical health problems; 3) bodily pain; 4) general health	Baseline, Months 1, 3, 6, and 9

Difference (MCID) in Health Assessment Questionnaire Short Form 36 (SF-36) Physical Component Summary (PCS) Scores at 1, 3, 6, and 9 Months	perceptions; 5) vitality; 6) limitations in social functioning because of physical or emotional problems; 7) limitations in usual role due to emotional problems; and 8) general mental health. Items 1-4 primarily contribute to the physical component summary score (PCS) of the SF-36. Items 5-8 primarily contribute to the mental component summary score (MCS) of the SF-36. Scores on each item are summed and averaged (range = 0 "worst"-100 "best"). Increases from baseline indicate improvement. Assessments were conducted at baseline, 1 month, 6 months, and 9 months. The percentage of participants achieving MCID in the SF-36 PCS was defined as an increase in PCS of at least 3 points from the baseline score.	
Percentage of Participants Achieving Minimal Clinically Important Difference (MCID) in Health Assessment Questionnaire Short Form 36 (SF-36) Mental Component Summary (MCS) Scores at 1, 3, 6, and 9 Months	The Health Assessment Questionnaire Short Form 36 (SF-36) determines participants overall quality of life by assessing 1) limitations in physical functioning due to health problems; 2) limitations in usual role because of physical health problems; 3) bodily pain; 4) general health perceptions; 5) vitality; 6) limitations in social functioning because of physical or emotional problems; 7) limitations in usual role due to emotional problems; and 8) general mental health. Items 1-4 primarily contribute to the physical component summary score (PCS) of the SF-36. Items 5-8 primarily contribute to the mental component summary score (MCS) of the SF-36. Scores on each item are summed and averaged (range = 0 "worst"-100 "best"). Increases from baseline indicate improvement. Assessments were conducted at baseline, 1 month, 6 months, and 9 months. The percentage of participants achieving MCID in the SF-36 MCS was defined as an increase in MCS of at least 5 points from the baseline score.	Baseline, Months 1, 3, 6, and 9

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

AbbVie (prior sponsor, Abbott)

Collaborators

- Raffeiner GmbH

Investigators

- Study Director: AbbVie Inc, AbbVie

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

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Study Record Dates

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Study Registration Dates

First Submitted

2011-07-01

First Submitted that Met QC Criteria
2011-07-22

First Posted (Estimated)
2011-07-25

Results Reporting Dates

Results First Submitted
2017-05-12

Results First Submitted that Met QC Criteria
2017-05-12

Results First Posted
2017-10-04

Study Record Updates

Last Update Submitted that met QC Criteria
2017-05-12

Last Update Posted
2017-10-04

Last Verified
2017-05

More Information

Terms related to this study

Keywords Provided by AbbVie (AbbVie (prior sponsor, Abbott))

Monoclonals
Moderate to severe plaque psoriasis
Psoriasis Area & Severity Index (PASI)
Adalimumab
Biological disease modifying anti rheumatic drugs (BDMARD)
Co morbidities
Antibodies
Disease Life Quality Index (DLQI)

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by AbbVie (AbbVie (prior sponsor, Abbott))

Related Info (http://rxabbvie.com)

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Record 1 of 1

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COMPLETED

A Dose Ranging Study of AIN457 in Patients With Moderate to Severe Chronic Plaque-type Psoriasis

ClinicalTrials.gov ID **NCT01071252**

Sponsor Novartis Pharmaceuticals

Information provided by Novartis (Novartis Pharmaceuticals) (Responsible Party)

Last Update Posted 2015 02 16

Study Details Tab

Study Overview

Brief Summary

The purpose of the study is to determine whether, in patients with moderate to severe plaque type psoriasis, AIN457 administered subcutaneously reduces the severity of psoriasis symptoms and the extent to which the patient s body area is affected by the disease (compared to placebo).

Feedback

Official Title

A Randomized, Double blind, Placebo Controlled, Multicenter Dose Ranging Study of Subcutaneously Administered AIN457, Assessing Psoriasis Area and Severity Index (PASI) Response in Patients With Moderate to Severe Chronic Plaque type Psoriasis

Conditions

Chronic Plaque type Psoriasis

Intervention / Treatment

- Drug: AIN457
- Drug: Placebo

Other Study ID Numbers

- CAIN457A2220
- 2009 016807 42

Study Start

2010 03

Primary Completion (Actual)

2011 02

Study Completion (Actual)

2011 02

Enrollment (Actual)

125

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

California Locations

San Diego, California, United States, 92123
Novartis Investigative Site

Kentucky Locations

Louisville, Kentucky, United States, 40217
Novartis Investigative Site

New York Locations

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

Chronic plaque type psoriasis diagnosed for at least 6 months at time of randomization

At randomization, moderate to severe psoriasis as defined by:

- PASI score of 12 or greater and,
- IGA score of 3 or greater and,
- Body Surface Area (BSA) affected by plaque type psoriasis of 10% or greater At screening and randomization, chronic plaque type psoriasis considered inadequately controlled by topical treatment.

Exclusion Criteria:

- Forms of psoriasis other than chronic plaque type
- Drug induced psoriasis (e.g., new onset or current exacerbation from beta blockers, calcium channel inhibitors or lithium) at randomization
- Previous exposure to AIN457
- Ongoing use of prohibited psoriasis treatments / medications and other prohibited medication at randomization. Washout periods detailed in the protocol have to be adhered to
- Known immunosuppression (e.g., AIDS) at screening and / or randomization
- History or evidence of active tuberculosis at screening
- Active systemic infections (other than common cold)
- History or symptoms of malignancy of any organ system, treated or untreated, within the past 5 years.
- Any severe, progressive or uncontrolled medical condition at randomization that in the judgment of the investigator prevents the patient from participating in the study
- Any clinically significant abnormal laboratory tests at randomization, that in the judgment of the investigator prevents the patient from participating in the study
- Inability or unwillingness to undergo repeated venipuntures
- History or evidence of drug or alcohol abuse
- Pregnant or nursing (lactating) women

Other protocol defined inclusion/exclusion criteria may apply

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: AIN457 1x25mg	Drug: AIN457
Experimental: AIN457 3x25mg	Drug: AIN457
Experimental: AIN457 3x75mg	Drug: AIN457
Experimental: AIN457 3x150mg	Drug: AIN457
Placebo Comparator: Placebo	Drug: Placebo

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants of Reponders of Psoriasis Area and Severity Index (PASI) 75 Achievement at Week 13	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each	week 13

	area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4).	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With Investigator s Global Assessment (IGA) Response	IGA treatment response is defined as achievement of IGA 0 (clear) or 1 (almost clear) and improvement of at least 2 points on the IGA scale compare with baseline.	Week 2, 3, 5, 9, 13, 17, 21, 25, 29, 33, 37
Percentage of Participants Achieving Psoriasis Area and Severity Index (PASI 50, PASI 75 or PASI 90)	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4).	Week 2, 3, 5, 9, 13, 17, 21, 25, 29, 33, 37
To Assess the Time to Relapse	Relapse is defined as the loss of at least 50% of the maximum PASI change from baseline achieved at any time before that visit and analyzed only for the active treatment groups.	37 weeks

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Novartis Pharmaceuticals

Collaborators

No information provided

Investigators

- Study Director: Novartis Pharmaceuticals, Novartis Pharmaceuticals

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2010-02-18

First Submitted that Met QC Criteria
2010-02-18

First Posted (Estimated)
2010-02-19

Results Reporting Dates

Results First Submitted
2015-01-28

Results First Submitted that Met QC Criteria
2015-02-12

Results First Posted (Estimated)
2015-02-16

Study Record Updates

Last Update Submitted that met QC Criteria
2015-02-12

Last Update Posted (Estimated)
2015-02-16

Last Verified
2015-02

More Information

Terms related to this study

Keywords Provided by Novartis (Novartis Pharmaceuticals)

Moderate to severe chronic plaque type psoriasis
AIN457
dermatology

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by Novartis (Novartis Pharmaceuticals)

Click here for more information about this study: (http://www.novartisclinicaltrials.com)

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full disclaimer (https://clinicaltrials.gov/about site/disclaimer) for details.

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

TERMINATED

Business decision due to slow enrollment

Etanercept Treatment in Patients With Moderate to Severe Plaque Psoriasis Who Lost Response to Adalimumab

ClinicalTrials.gov ID **NCT01543204**

Sponsor Amgen

Information provided by Amgen (Responsible Party)

Last Update Posted 2017 12 29

Study Details Tab

Study Overview

Brief Summary

This study will evaluate the efficacy of etanercept in patients with plaque psoriasis who have lost a satisfactory response to adalimumab.

Feedback

Official Title

Open Label Study to Evaluate the Efficacy of Etanercept Treatment in Subjects With Moderate to Severe Plaque Psoriasis Who Have Lost a Satisfactory Response to Adalimumab

Conditions

Psoriasis

Intervention / Treatment

- Drug: Etanercept

Other Study ID Numbers

- 20101145

Study Start (Actual)

2012 02 01

Primary Completion (Actual)

2015 05 29

Study Completion (Actual)

2015 05 29

Enrollment (Actual)

64

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Etanercept (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Etanercept) Adalimumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Adalimumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Alabama Locations

Birmingham, Alabama, United States, 35205
Research Site

Mobile, Alabama, United States, 36609
Research Site

Arizona Locations

Phoenix, Arizona, United States, 85044

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Moderate to severe plaque psoriasis
- Loss of satisfactory response to adalimumab
- Currently receiving or recently discontinued treatment with adalimumab

Exclusion Criteria:

- Active skin conditions that would interfere with evaluations of the effect of investigational product on psoriasis
- Serious medical conditions

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : N/A
Interventional Model : Single Group Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Etanercept 50 mg Participants received etanercept 50 mg, twice weekly (BIW), subcutaneously (SC) for 12 weeks followed by 50 mg, once weekly (QW), SC for an additional 12 weeks.	Drug: Etanercept • Administered by subcutaneous injection • Other Names: ◦ Enbrel®

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With an sPGA Score of 0 (Clear) or 1 (Almost Clear) at Week 12	The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity of disease (induration, scaling, and erythema). A sPGA response is defined as a sPGA value of clear (score 0) or almost clear (score 1).	Week 12
Percentage of Participants With an sPGA Score of 0 (Clear) or 1 (Almost Clear) at Week 12 by Anti-	The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity of disease (induration, scaling, and erythema). A sPGA response is defined as a sPGA value of clear (score 0) or almost clear (score 1).	Week 12

adalimumab Antibody Status		

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With an sPGA Score of 0 (Clear) or 1 (Almost Clear) at All Other Visits	The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity of disease (induration, scaling, and erythema). A sPGA response is defined as a sPGA value of clear (score 0) or almost clear (score 1).	Weeks 4, 8, 16, 20 and 24
Percentage of Participants With an sPGA Score of 0 (Clear) or 1 (Almost Clear) at All Other Visits by Anti-adalimumab Antibody Status	The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity of disease (induration, scaling, and erythema). A sPGA response is defined as a sPGA value of clear (score 0) or almost clear (score 1).	Weeks 4, 8, 16, 20 and 24
Percentage of Participants With an sPGA Score of 0, 1 or 2 at Each Visit	The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity of disease (induration, scaling, and erythema). The percentage of participants with a score of 0 (clear), 1 (almost clear) or 2 (mild) is reported.	Weeks 4, 8, 12, 16, 20 and 24
Percentage of Participants With an sPGA Score of 0, 1 or 2 by Anti-	The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity of disease (induration, scaling, and erythema). The percentage of participants with a	Weeks 4, 8, 12, 16, 20 and 24

adalimumab Antibody Status at Each Visit	score of 0 (clear), 1 (almost clear) or 2 (mild) is reported.	
Static Physician Global Assessment (sPGA) at Each Visit	The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity of disease (induration, scaling, and erythema).	Weeks 4, 8, 12, 16, 20 and 24
Static Physician Global Assessment (sPGA) by Anti-adalimumab Antibody Status at Each Visit	The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity of disease (induration, scaling, and erythema).	Weeks 4, 8, 12, 16, 20 and 24
Percentage of Participants With a PASI 50 Response at Each Visit	A PASI 50 response is a 50% or greater improvement (reduction) from baseline in PASI score. The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0 to 72, with higher scores indicating greater severity and/or more extensive psoriasis.	Baseline and Weeks 4, 8, 12, 16, 20 and 24
Percentage of Participants With a PASI 50 Response by Anti-adalimumab Antibody Status at Each Visit	A PASI 50 response is a 50% or greater improvement (reduction) from baseline in PASI score. The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0 to 72, with higher	Baseline and weeks 4, 8, 12, 16, 20 and 24

	scores indicating greater severity and/or more extensive psoriasis.	
Percentage of Participants With a PASI 75 Response at Each Visit	A PASI 75 response is a 75% or greater improvement (reduction) from baseline in PASI score. The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0 to 72, with higher scores indicating greater severity and/or more extensive psoriasis.	Baseline and Weeks 4, 8, 12, 16, 20 and 24
Percentage of Participants With a PASI 75 Response by Anti-adalimumab Antibody Status at Each Visit	A PASI 75 response is a 75% or greater improvement (reduction) from baseline in PASI score. The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0 to 72, with higher scores indicating greater severity and/or more extensive psoriasis.	Baseline and weeks 4, 8, 12, 16, 20 and 24
Percentage of Participants With a PASI 90 Response at Each Visit	A PASI 90 response is a 90% or greater improvement (reduction) from baseline in PASI score. The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0 to 72, with higher scores indicating greater severity and/or more extensive psoriasis.	Baseline and Weeks 4, 8, 12, 16, 20 and 24

Percentage of Participants With a PASI 90 Response by Anti-adalimumab Antibody Status at Each Visit	A PASI 90 response is a 90% or greater improvement (reduction) from baseline in PASI score. The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0 to 72, with higher scores indicating greater severity and/or more extensive psoriasis.	Baseline and weeks 4, 8, 12, 16, 20 and 24
Percentage of Participants With at Least a 1 Grade Improvement in sPGA From Baseline	The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity of disease (induration, scaling, and erythema). The percentage of participants with an improvement from baseline of ≥ 1 grade is reported.	Baseline and Weeks 4, 8, 12, 16, 20 and 24
Percentage of Participants With at Least a 1 Grade Improvement in sPGA From Baseline by Anti-adalimumab Antibody Status	The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity of disease (induration, scaling, and erythema). The percentage of participants with an improvement from baseline of ≥ 1 grade is reported.	Baseline and weeks 4, 8, 12, 16, 20 and 24
Percentage of Participants With at Least a 2 Grade Improvement in sPGA From Baseline	The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity of disease (induration, scaling, and erythema). The percentage of participants with an improvement from baseline of ≥ 2 grades is reported.	Baseline and Weeks 4, 8, 12, 16, 20 and 24

Percentage of Participants With at Least a 2 Grade Improvement in sPGA From Baseline by Anti-adalimumab Antibody Status	The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity of disease (induration, scaling, and erythema). The percentage of participants with an improvement from baseline of ≥ 2 grades is reported.	Baseline and weeks 4, 8, 12, 16, 20 and 24
Percent Change From Baseline in Psoriasis Area and Severity Index (PASI)	The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0 to 72, with higher scores indicating greater severity and/or more extensive psoriasis. Percent change from baseline was calculated as (Baseline Value - Post-baseline Value) / Baseline Value * 100, hence a positive value indicates improvement.	Baseline and Weeks 4, 8, 12, 16, 20 and 24
Percent Change From Baseline in PASI by Anti-adalimumab Antibody Status	The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0 to 72, with higher scores indicating greater severity and/or more extensive psoriasis. Percent change from baseline was calculated as (Baseline Value - Post-baseline Value) / Baseline Value * 100, hence a positive value indicates improvement.	Baseline and weeks 4, 8, 12, 16, 20 and 24
Percent Change From Baseline in the	A measurement of psoriasis involvement, given as the physician s assessment of the percentage of the participant s total body surface area (BSA)	Baseline and Weeks

Percentage of Body Surface Area (BSA) Involved With Psoriasis	involved with psoriasis. The percent of BSA affected was estimated by assuming that the participant s palm, excluding the fingers and thumb, represented roughly 1% of the body s surface. Percent change from baseline was calculated as (Baseline Value - Post-baseline Value) / Baseline Value * 100, hence a positive value indicates improvement.	4, 8, 12, 16, 20 and 24
Percent Change From Baseline in the Percentage of BSA Involved With Psoriasis by Anti-adalimumab Antibody Status	A measurement of psoriasis involvement, given as the physician s assessment of the percentage of the participant s total body surface area (BSA) involved with psoriasis. The percent of BSA affected was estimated by assuming that the participant s palm, excluding the fingers and thumb, represented roughly 1% of the body s surface. Percent change from baseline was calculated as (Baseline Value - Post-baseline Value) / Baseline Value * 100, hence a positive value indicates improvement.	Baseline and weeks 4, 8, 12, 16, 20 and 24
Patient Satisfaction With Treatment at Week 12	Participants indicated their level of satisfaction with the medication s control of psoriasis on a scale from "very dissatisfied" to "very satisfied".	Week 12
Patient Satisfaction With Treatment at Week 24	Participants indicated their level of satisfaction with the medication s control of psoriasis on a scale from "very dissatisfied" to "very satisfied".	Week 24
Change From Baseline in Dermatology Life Quality Index (DLQI) Total Score	The dermatology life quality index (DLQI) is a skin disease-specific instrument to evaluate health-related quality of life. The DLQI questionnaire asks participants to evaluate the degree that psoriasis has affected their quality of life in the last week, and includes the following parameters: symptoms and feelings, daily activities, leisure activities, work or school activities, personal relationships and treatment	Baseline and Weeks 12 and 24

	related feelings. Participants answered 10 questions on a scale from 0 (not at all) to 3 (very much); the range of the total score is from 0 (best possible score) to 30 (worst possible score). Change from baseline was calculated as Baseline Value - Post-baseline Value, hence a positive change indicates improvement.	
Change From Baseline in Work Productivity and Activity Impairment (WPAI)	The impact of disease severity on the participant s ability to participate in work and other activities was evaluated using the WPAI. WPAI consists of six questions to assess whether the participant was currently employed (Q1); how many hours from work were missed due to problems associated with psoriasis (Q2) or any other reason (Q3); hours actually worked (Q4); degree that psoriasis affected productivity while working (Q5); and degree that psoriasis affected regular activities (Q6) over the past 7 days. Four separate overall scores were calculated, including absenteeism (work time missed due to health), presenteeism (impairment at work due to health), work productivity loss (overall work impairment due to health), and activity impairment due to health. Each score ranges from 0 to 100 with higher scores indicating greater impairment and less productivity. Change from baseline was calculated as Baseline Value - Post-baseline Value, hence a positive change indicates improvement.	Baseline and Weeks 12 and 24
Change From Baseline in Patient Assessment of Itch	The severity of the participants itch was individually assessed by the participant. Participants were asked to circle a number between 0 and 10 to describe their itch, with 0 indicating "no itch at all" and 10 indicating "worst itch imaginable." Change from baseline was calculated as Baseline Value - Post-baseline	Baseline and Week 12 and 24

	Value, hence a positive change indicates improvement.	
Change From Baseline in Patient Assessment of Pain	The severity of the participants pain was individually assessed by the participant. Participants were asked to circle a number between 0 and 10 to describe how much their psoriasis hurts today, with 0 indicating "does not hurt at all" and 10 indicating "worst hurt imaginable." Change from baseline was calculated as Baseline Value - Post-baseline Value, hence a positive change indicates improvement.	Baseline and Week 12 and 24
Change From Baseline in Patient Assessment of Flaking	The severity of the participants pain was individually assessed by the participant. Participants were asked to circle a number between 0 and 10 to describe their flaking, with 0 indicating "no flaking at all" and 10 indicating "worst flaking imaginable." Change from baseline was calculated as Baseline Value - Post-baseline Value, hence a positive change indicates improvement.	Baseline and Week 12 and 24
Number of Participants With Adverse Events	A treatment-related adverse event is defined as an event that is deemed by the investigator to be related to investigational product.	From first dose of study drug until 30 days after the last dose (up to 28 weeks)

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Amgen

Collaborators

No information provided

Investigators

- Study Director: MD, Amgen

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

- Bagel J, Tyring S, Rice KC, Collier DH, Kricorian G, Chung J, Iles J, Stolshek BS, Kaliyaperumal A, Papp KA. Open label study of etanercept treatment in patients with moderate to severe plaque psoriasis who lost a satisfactory response to adalimumab. Br J Dermatol. 2017 Aug;177(2):411 418. doi: 10.1111/bjd.15381. Epub 2017 Jul 19. (https://pubmed.ncbi.nlm.nih.gov/28196270)

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted

2012-01-17

First Submitted that Met QC Criteria

2012-02-27

First Posted (Estimated)

2012-03-02

Results Reporting Dates

Results First Submitted

2016-05-18

Results First Submitted that Met QC Criteria

2016-05-18

Results First Posted (Estimated)

2016-06-27

Study Record Updates

Last Update Submitted that met QC Criteria

2017-12-05

Last Update Posted

2017-12-29

Last Verified

2017-12

More Information

Terms related to this study

Keywords Provided by Amgen

plaque psoriasis
etanercept
adalimumab

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous

Skin Diseases
Psoriasis
Anti Inflammatory Agents, Non Steroidal
Analgesics, Non Narcotic
Analgesics
Sensory System Agents
Peripheral Nervous System Agents
Physiological Effects of Drugs
Anti Inflammatory Agents
Antirheumatic Agents
Gastrointestinal Agents
Immunosuppressive Agents
Immunologic Factors
Etanercept

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by Amgen

AmgenTrials clinical trials website (http://www.amgentrials.com)

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full disclaimer (https://clinicaltrials.gov/about site/disclaimer) for details.

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Infliximab in High Need Versus Low Need Psoriasis Patients: The IHELP Study (Study P04320)(COMPLETED)

ClinicalTrials.gov ID **NCT00254982**

Sponsor Merck Sharp & Dohme LLC

Information provided by Merck Sharp & Dohme LLC (Responsible Party)

Last Update Posted 2015 10 12

Study Details Tab

Study Overview

Brief Summary

Feedback

This is an open label, multicenter, parallel group comparison study of the efficacy, safety, and tolerability of infliximab therapy in adult patients suffering from chronic plaque psoriasis (psoriasis vulgaris). Patients will be assigned to GROUP I ("high need") or GROUP II ("low need") by the investigator according to their previous psoriasis treatment.

Official Title

An Open Label Study to Determine Equivalence in Efficacy, Organ Safety and Systemic Tolerability Between Infliximab in GROUP I ("High Need") and GROUP II ("Low Need") Patients Suffering From Chronic Plaque Psoriasis (Psoriasis Vulgaris)

Conditions

Psoriasis

Intervention / Treatment

- Biological: Infliximab

Other Study ID Numbers

- P04320
- 2005 001243 28 (EudraCT Number)

Study Start

2005 08

Primary Completion (Actual)

2006 09

Study Completion (Actual)

2006 09

Enrollment (Actual)

593

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Infliximab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Infliximab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

No location data

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Written informed consent by the patient for study participation, prior to protocol specific procedures.
- Patients who are 18 years of age or older at time of enrollment, may be male or female and of any race.
- Diagnosis of plaque type psoriasis (psoriasis vulgaris) at least 6 months prior to screening.
- Plaque type psoriasis covering at least 10% of total body surface area.
- Psoriasis Area and Severity Index (PASI) Score of 12 or greater.
- GROUP I ("high need") patients: adult patients with moderate to severe plaque psoriasis who are either not controlled by, or are intolerant to or have contraindications to at least two currently available systemic therapies (e.g. photochemotherapy, cyclosporine, methotrexate, oral retinoids, fumaric acid esters, efalizumab, etanercept). GROUP II ("low need") patients: adult patients with moderate to severe plaque psoriasis who have undergone pre treatment with no more than one currently available systemic therapy (e.g. photochemotherapy, cyclosporine, methotrexate, oral retinoids, fumaric acid esters, efalizumab, etanercept). A patient showing contraindications towards two systemic treatments, who has never been pretreated with a systemic therapy will be assigned to GROUP II ("low need").
- Patients must have had a chest x ray (preferably posteroanterior and lateral) within 3 months prior to first infusion with no evidence of malignancy, infection (e.g. tuberculosis) or fibrosis.
- Laboratory test results: liver enzymes (aspartate aminotransferase (AST), alanine aminotransferase (ALT), gamma glutamyl transferase (GGT) and alkaline phosphatase) must be within 1.5 times the upper limit of normal range (ULN), total bilirubin <=1.0 ULN, serum creatinine <1.5 mg/dL (must be available at Baseline).
- Patients must agree to avoid prolonged sun exposure or other ultraviolet light sources during the study.
- Women of child bearing potential must agree to use a medically accepted method of contraception prior to screening, while receiving protocol specified medication, and for six months after stopping the medication. Acceptable methods of contraception include abstinence, condoms (male or female) with or without a spermicidal agent, diaphragm or cervical cap with spermicide, medically prescribed intrauterine device (IUD), oral or injectable hormonal contraceptive, and surgical sterilization (e.g. hysterectomy or tubal ligation).
- Women of child bearing potential must have a negative serum pregnancy test (beta human chorionic gonadotropin [hCG]) at Screening (must be available at Baseline).
- Baseline PASI Score of 12 or greater.

Exclusion Criteria:

- Patients suffering from active or latent tuberculosis. Prior to the start of treatment with infliximab tuberculosis needs to be excluded following the recommendations published

by the German Paul Ehrlich Institute.

- Patients who have had or have a serious infection (e.g. abscess, pneumonia or pyelonephritis) or who have been hospitalized or received treatment with intravenous antibiotics during the previous 2 months.
- Patients who are known to be infected with human immunodeficiency virus, hepatitis B or C virus, prior or current opportunistic infections (within the last six months, Herpes zoster within the last 2 months).
- Patients suffering from congestive heart failure including medically controlled asymptomatic patients.
- History of demyelinating disease or symptoms suggestive of multiple sclerosis or optic neuritis.
- Patients who have current signs and symptoms or history of systemic lupus erythematosus.
- Patients suffering from non plaque psoriasis, e.g. erythrodermic, guttate or pustular forms. The presence of psoriasis arthritis is no exclusion criterion.
- Patients suffering from current drug induced psoriasis (e.g. a new onset of psoriasis or an exacerbation of psoriasis from beta blockers or calcium channel blockers). If the patient takes one of those substances on a regular basis, it should be on a stable dose for at least three weeks prior to Baseline.
- Patients suffering from severe, progressive or uncontrolled renal, hepatic, hematological, gastrointestinal, endocrine, pulmonary, cardiac, neurological, cerebral or psychiatric diseases, that, in the opinion of the investigator, would interfere with the study evaluations or safe or optimal participation in the study.
- Any known malignancy during the last five years (except basal cell carcinoma), any history of lymphoproliferative disease.
- Patients who have received any systemic psoriasis therapy (e.g. immunosuppressant) or lithium within 28 days or baseline visit.
- Patients pretreated with etanercept or efalizumab within 28 days of Baseline.
- Patients previously treated with infliximab.
- Patients who have used topical treatments that could affect PASI evaluation (e.g. corticosteroids, anthralin, topical vitamin D derivates) within 2 weeks of baseline visit, except special areas like head or hands.
- Patients who have used any investigational drug within 3 months of Baseline.
- Patients with allergy/sensitivity to study drug or its excipients.
- Women who are breast feeding, pregnant, or intend to become pregnant.
- Patients with any clinically significant condition or situation, other than the condition being studied.
- Patients who are participating in any other clinical study.
- Patients who are part of the staff personnel directly involved with this study.
- Patients who are a family member of the investigational study staff.
- Patients who have used any investigational drug within 3 months before Baseline.
- Patients who have received any systemic psoriasis therapy (e.g. immunosuppressants) or lithium within 28 days of baseline visit.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Non Randomized
Interventional Model : Parallel Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment

Experimental: Group 1 (high-need)
 	
Adult participants with moderate to severe plaque psoriasis who were either not controlled by, or were intolerant to or had contraindications to at least two currently available systemic therapies (eg, photochemotherapy, cyclosporine, methotrexate, oral retinoids, fumaric acid esters, efalizumab, etanercept).
	Biological: Infliximab
	
	• Infliximab 5 mg/kg was given as an induction regimen at week 0, 2, and 6 weeks after the first infusion and then at week 14.
	
	• Other Names:
	  ◦ Remicade
	  ◦ SCH 215596

Experimental: Group II (low-need)
 	
Adult participants with moderate to severe plaque psoriasis who had undergone pretreatment with no more than one currently available systemic therapy (eg, photochemotherapy, cyclosporine, methotrexate, oral retinoids, fumaric acid
	Biological: Infliximab
	
	• Infliximab 5 mg/kg was given as an induction regimen at week 0, 2, and 6 weeks after the first infusion and then at week 14.
	
	• Other Names:
	  ◦ Remicade
	  ◦ SCH 215596

esters, efalizumab, etanercept).	

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Proportion of Participants Achieving a Greater Than or Equal to 75% Improvement in Psoriasis Area and Severity Index (PASI75) Score	PASI75 response is defined as participants who achieved at least a 75% improvement in PASI score from Baseline to Week 22. The PASI is a system used for assessing and grading the severity of psoriatic lesions and their responses to therapy. The PASI produces a numeric score that can range from 0 to 72 (the higher the number, the worse the disease).	Baseline and Week 22

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Merck Sharp & Dohme LLC

Collaborators

- Essex Pharma GmbH
- Centocor, Inc.

Investigators

No information provided

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2005-11-15

First Submitted that Met QC Criteria
2005-11-16

First Posted (Estimated)
2005-11-17

Results Reporting Dates

Results First Submitted
2010-05-27

Results First Submitted that Met QC Criteria
2010-05-27

Results First Posted (Estimated)
2010-07-05

Study Record Updates

Last Update Submitted that met QC Criteria
2015-10-09

Last Update Posted (Estimated)
2015-10-12

Last Verified
2015-10

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Tumor Necrosis Factor Inhibitors
Anti Inflammatory Agents
Dermatologic Agents
Gastrointestinal Agents
Antirheumatic Agents
Infliximab

Study Documents

No study documents available

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COMPLETED

Desoximetasone Spray 0.25%, Hypothalamic Pituitary Adrenal (HPA) Axis Study

ClinicalTrials.gov ID **NCT01043393**

Sponsor Taro Pharmaceuticals USA

Information provided by Taro Pharmaceuticals USA (Responsible Party)

Last Update Posted 2014 06 02

Study Details Tab

Study Overview

Brief Summary

Feedback

The objective of this study is to evaluate the potential of desoximetasone 0.25% topical spray to suppress HPA axis function. The potential for adrenal suppression will be assessed following multiple dosing with Desoximetasone 0.25% Topical Spray in patients with moderate to severe plaque psoriasis. The secondary objectives are to evaluate the efficacy parameters and to evaluate the adverse event (AE) profile.

Official Title

An Open Label, Safety/Efficacy Study to Assess the Potential for Adrenal Suppression Following Multiple Dosing With Desoximetasone 0.25% Topical Spray in Patients With Moderate to Severe Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Desoximetasone 0.25% spray

Other Study ID Numbers

- DSXS 0805
- Study # 70915005 (Other Identifier) (OTHER: Novum)

Study Start

2010 02

Primary Completion (Actual)

2010 06

Study Completion (Actual)

2010 06

Enrollment (Actual)

24

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Secondary Adrenal Insufficiency (https://rarediseases.info.nih.gov/diseases/12735/secondary adrenal insufficiency)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Desoximetasone (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Desoximetasone)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Arkansas Locations

Hot Springs, Arkansas, United States
Investigator Site

New Mexico Locations

Albuquerque, New Mexico, United States
Investigator Site

South Carolina Locations



Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Have a definite clinical diagnosis of stable plaque psoriasis with the extent of BSA affected as designated for each group
- Group 1: involvement of 10 15% of their BSA
- Group 2: involvement of > 15% of their BSA
- Have a Physicians Global Assessment (PGA) score of 3 (moderate) or 4 (severe) at baseline for the overall disease severity.
- Results from a cortisol response test that are considered normal and show no evidence of any abnormal HPA function or adrenal response. Patients must fulfill all of these stipulations:

Exclusion Criteria:

- Female who is pregnant, nursing, planning to become pregnant during the duration of the study, or if of child bearing potential and sexually active not prepared to use appropriate contraceptive methods to avoid pregnancy.
- Patient has current diagnosis of types of psoriasis other than stable plaque psoriasis (i.e. acute, guttate, erythrodermic, exfoliative or pustular psoriasis) or has psoriasis of any kind on the face or scalp that will require active treatment during the study.
- Patient has a history of psoriasis that has been unresponsive to topical corticosteroid therapy.
- In the Investigator s opinion, the patient has other dermatological conditions, such as atopic or contact dermatitis, that may interfere with the clinical assessments of the signs and symptoms of psoriasis
- Patient has a history of allergy or sensitivity to corticosteroids or history of any drug hypersensitivity or intolerance which, in the opinion of the Investigator, would compromise the safety of the patient or the results of the study.
- Patient has a history of an adverse reaction to CortrosynTM or similar test reagents.
- Patient has a significant history or current evidence of chronic infectious disease, system disorder, organ disorder or other medical condition that in the Investigator s opinion would place the study patient at undue risk by participation in the study.
- Patient is currently receiving or has received any radiation therapy, anti neoplastic agents or immunosuppressant medication within 4 weeks prior to the first dose of study drug.
- Patient has undergone treatment with any systemic or photo antipsoriatic therapy within 8 weeks of the first dose of study drug.
- Patient has been treated within 12 weeks (or five half lives whichever is less) prior to the first dose of study drug with any biological therapies for psoriasis.
- Patient has received any systemic steroids within 4 weeks of the first dose of the study drug.
- Patients who have used any topical antipsoriatic agents of any kind or any topical corticosteroids for any reason within 2 weeks prior to first use of study drug

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Non Randomized
Interventional Model : Parallel Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Psoriasis involving 10-15% BSA Patients 18 years of age or older with a confirmed diagnosis of moderate to severe plaque psoriasis having involvement of 10-15% of their body surface area.	Drug: Desoximetasone 0.25% spray • Desoximetasone spray applied to affected areas twice daily for 28 days
Experimental: Psoriasis involving >15% of BSA Patients 18 years of age or older with a confirmed diagnosis of moderate to severe plaque psoriasis having involvement of >15% of their body surface area.	Drug: Desoximetasone 0.25% spray • Desoximetasone spray applied to affected areas twice daily for 28 days

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Proportion of Patients in the	Each patient is assessed at Day 28. A cortisol response test performed at baseline are	28 days

Study With Hypothalamic Pituitary Adrenal (HPA) Axis Suppression	reevaluated at the conclusion of the study. If the normal cortisol response test measured at baseline is no long present the patient is considered to have demonstrated possible HPA axis suppression.	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Baseline in Percent Body Surface Area (%BSA) Affected by Psoriasis	Body Surface Area (BSA) is a numerical score used to measure the physician s assessment of the percentage of the participant s total BSA involved with psoriasis. BSA = SQRT ((height (cm) X weight (kg))/3600) BSA is in m2, W is weight in kg, and H is height in cm. Total body Surface Area (BSA) in meters squared %Body Surface Area Affected the "Rule of Nine" was be used	28 days
Change From Baseline in Physician s Global Assessment (PGA) Score for Psoriasis	The PGA scale is designed to evaluate the physician s global assessment of the participant s psoriasis based on severity of induration,erythema and scaling. The PGA is assessed on a scale of 0 to 5 (0 = clear, 5 = severe).	28 days

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Taro Pharmaceuticals USA

Collaborators

No information provided

Investigators

No information provided

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

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Study Registration Dates

First Submitted
2010-01-04

First Submitted that Met QC Criteria
2010-01-04

First Posted (Estimated)
2010-01-06

Results Reporting Dates

Results First Submitted
2014-01-22

Results First Submitted that Met QC Criteria
2014-05-05

Results First Posted (Estimated)
2014-06-02

Study Record Updates

Last Update Submitted that met QC Criteria
2014-05-05

Last Update Posted (Estimated)
2014-06-02

Last Verified
2014-05

More Information

Terms related to this study

Keywords Provided by Taro Pharmaceuticals USA

Plaque psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Anti Inflammatory Agents
Glucocorticoids
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Physiological Effects of Drugs
Desoximetasone

Study Documents

No study documents available

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Record 1 of 1

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COMPLETED

Open Label Study Etanercept's Maintenance Dose in Obese Patients With Moderate to Severe Plaque Type Psoriasis

ClinicalTrials.gov ID **NCT00800982**

Sponsor University of California, San Francisco

Information provided by University of California, San Francisco (Responsible Party)

Last Update Posted 2013 05 07

Study Details Tab

Study Overview

Brief Summary

Feedback

This is a single center, open label, pilot study. A total of 30 subjects (15 in each study arm) will be enrolled in this 6 month study to evaluate whether the addition of narrow band UVB (NB UVB) phototherapy can enhance the efficacy of etanercept s maintenance dose, 50 mg once a week, in obese psoriasis patients.

Detailed Description

In Phase I, all subjects will receive etanercept s induction dose, 50 mg twice a week, for a total of 12 weeks. In Phase II, all subjects will receive etanercept s maintenance dose, 50 mg once a week, during Weeks 12 24. Those subjects randomized to the treatment arm will receive NB UVB phototherapy 3 times a week during Phase II. In order to ensure homogeneity between the NB UVB arm and non NB UVB arm, subjects will be randomized according to their Body Mass Index (BMI). The Psoriasis Area Severity Index (PASI) score and Physician Global Assessment (PGA) will be calculated at each visit to determine the effectiveness of the etanercept and NB UVB treatment during both phases of the study. The hypothesis is that the combination of NB UVB phototherapy three times a week and etanercept maintenance dose (50 mg once a week) will enhance the efficacy of the maintenance dose alone in obese patients (BMI >30) with moderate to severe psoriasis.

Official Title

A Single Center, Open Label, Pilot Study to Evaluate the Efficacy and Tolerability of Narrow Band UVB Phototherapy in Enhancing Etanercept s Maintenance Dose in Obese Patients With Moderate to Severe Plaque Type Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Procedure: Narrow band (310 312 nm) ultraviolet light B phototherapy
- Drug: etanercept

Other Study ID Numbers

- KOO ENBREL 2008
- H5939 31693 01 (Other Identifier) (OTHER: UCSF Committee for Human Research)

Study Start

2008 10

Primary Completion (Actual)

2012 01

Study Completion (Actual)

2012 03

Enrollment (Actual)

30

Study Type

Interventional

Phase

Not Applicable

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Etanercept (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Etanercept)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

California Locations

San Francisco, California, United States, 94118

UCSF Psoriasis and Skin Treatment Center

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Nonimmunocompromised males or females 18 years of age or older.
- Must be able to read, understand, and speak basic English.
- Body Surface Area (BSA) involvement of greater than 10%.
- Psoriasis Area and Severity Index greater than 10.
- Obese defined as having a Body Mass Index greater than 30.
- Eligible for systemic therapy, particularly etanercept, and Narrow Band Ultraviolet B in the opinion of the investigator.
- Sign and date the appropriate written informed consent and Health Insurance Portability and Accountability Act authorization
- Negative urine pregnancy test within 7 days before the first dose of etanercept in all women (except those surgically sterile or at least 5 years postmenopausal).
- No evidence of active or latent tuberculosis based on a negative Purified Protein Derivative skin test. Patients with documentation of adequately treated tuberculosis may be enrolled.
- Sexually active subjects of childbearing potential must agree to use medically acceptable form of contraception during screening and throughout the study.
- Willing and able to self administer subcutaneous injections or to have a qualified person available to administer subcutaneous injections
- Agrees to comply with protocol requirements, attend all regularly study visits and is considered to be a good study subject
- Meets concomitant medication washout requirements

Exclusion Criteria:

- Erythrodermic, pustular, or guttate psoriasis
- Evidence of skin conditions other than psoriasis that would interfere with study related evaluations of psoriasis.
- Known sensitivity to any component of the study medications.
- Evidence of active infections such as fevers, chills, sweats, or history of untreated Lyme disease and active severe infections within 4 weeks before screening visit, or between the screening and Week 0 visits.
- Evidence of latent or active hepatitis B infection as indicated by positive HBsAg test during the screening visit.
- Personal or first degree family history of neurologic disease.
- Poorly controlled medical condition including, but not limited to, unstable cardiovascular disease, poorly controlled diabetes, recent stroke, history of recurrent infections, or any other condition for which, in the opinion of the investigator, participation in the study would place the subject at risk.
- History of any Tumor Necrosis Factor α inhibitor use including etanercept, infliximab, and adalimumab within 4 weeks of starting study drug.
- History of non cutaneous malignancy within the past 5 years.

- History of drug or alcohol abuse. Substance abuse must clearly be documented so those patients with a remote and minor history of drug/alcohol use will still have an opportunity to participate in the study.
- Female subjects who are not postmenopausal for at least 1 year, surgically sterile, or willing to practice effective contraception during the study. Nursing mothers, pregnant women and women planning to become pregnant while on study are to be excluded.
- Plans to receive any live vaccines during the study.
- Evidence of photosensitivity disorder (i.e. polymorphous light eruption).
- Known photosensitivity or known sensitivity to any of the excipients or products to be administered during dosing.
- Current enrollment in another clinical study and treatment with another experimental drug or approved therapy for experimental use within 30 days prior to Week 0
- Cannot commit to all the assessments required by the protocol
- Any disorder that compromises the ability of the subject to give written informed consent and/or to comply with study procedures
- Considered by the investigator, for any reason, to be an unsuitable candidate for study participation.
- Cannot or do not wish to comply with the protocol washout requirements (please see section below entitled "Washout Period Prior to Week 0).

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

Yes

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Active Comparator: 1 (Etanercept only) Subjects will only be treated with etanercept. This is given at the standard FDA approved dosage of 50 mg twice weekly x 3 months then 50 mg once weekly x 3 months. No UVB will be given. Sham UVB will not be used because the subjects are not blinded because they often know they are receiving sham UVB due to differences in light intensity and heat.	Drug: etanercept • Etanercept is given at the standard FDA approved dosage of 50 mg twice weekly x 3 months then 50 mg once weekly x 3 months. • Other Names: ◦ Enbrel

Experimental: 2 (Etanercept + nb-UVB)
 	
Subjects will receive etanercept. This is given at the standard FDA approved dosage of 50 mg twice weekly x 3 months then 50 mg once weekly x 3 months.
 	
In addition, for months 3-6, subjects will
	Procedure: Narrow band (310-312 nm) ultraviolet light B phototherapy
	
	• Narrow band (310-312 nm) ultraviolet light B phototherapy 3 times a week during Weeks 12-24. NB-UVB therapy will be adjusted according to the clinical judgment of the University of California San Francisco Psoriasis Treatment Center phototherapy staff
	
	• Other Names:
	  ◦ nb-UVB
	  ◦ nbUVB

receive Narrow Band Ultraviolet B phototherapy three times a week for 12 weeks in addition to the etanercept maintenance dose. The safety and efficacy of the combination therapy will be evaluated by the registered phototherapy nurses at each phototherapy visit and by the study investigator at monthly visits. NB-UVB therapy will be adjusted according to the clinical judgment of the University of California San Francisco Psoriasis Treatment Center phototherapy staff.	◦ narrowband UVB Drug: etanercept • Etanercept is given at the standard FDA approved dosage of 50 mg twice weekly x 3 months then 50 mg once weekly x 3 months. • Other Names: ◦ Enbrel

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Psoriasis Area Severity Index. This Scale Ranges From 0-72, 0 Being no Disease, and 72 Being Most Severe. The Number of Patients Who Achieved 75% Improvement of Their Psoriasis at the End of 24 Weeks Are Indicated in the Outcomes Data Below.	Psoriasis area severity index was used to determine the number of patients in each treatment arm who had 75% improvement in their psoriasis. This scale uses the characteristics of the psoriasis, such as body surface area, redness, thickness, and scaling, to determine the severity score.	Weeks 12-24

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

University of California, San Francisco

Collaborators

No information provided

Investigators

- Principal Investigator: John Koo, MD, UCSF Psoriasis and Skin Treatment Center, Department of Dermatology, University of California, San Francisco

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

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Study Record Dates

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Study Registration Dates

First Submitted
2008-05-13

First Submitted that Met QC Criteria
2008-12-02

First Posted (Estimated)
2008-12-03

Results Reporting Dates

Results First Submitted
2013-02-19

Results First Submitted that Met QC Criteria
2013-03-26

Results First Posted (Estimated)
2013-05-07

Study Record Updates

Last Update Submitted that met QC Criteria
2013-03-26

Last Update Posted (Estimated)
2013-05-07

Last Verified

2013-03

More Information

Terms related to this study

Keywords Provided by University of California, San Francisco

Obese patients (BMI>30)
Patients with moderate to severe psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Anti Inflammatory Agents, Non Steroidal
Analgesics, Non Narcotic
Analgesics
Sensory System Agents
Peripheral Nervous System Agents
Physiological Effects of Drugs
Anti Inflammatory Agents
Antirheumatic Agents
Gastrointestinal Agents
Immunosuppressive Agents
Immunologic Factors
Etanercept

Study Documents

No study documents available

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COMPLETED

Cardiovascular Effects in Psoriasis Patients Treated With Adalimumab.

ClinicalTrials.gov ID NCT01320293

Sponsor University of North Carolina, Chapel Hill

Information provided by Aida Lugo Somolinos, MD, University of North Carolina, Chapel Hill (Responsible Party)

Last Update Posted 2016 12 26

Study Details Tab

Study Overview

Brief Summary

Feedback

Severe psoriasis has been demonstrated to be associated with decreased endothelial function and an increase risk of future coronary events. Although systemic therapy with immunomodulatory agents has been shown to improve psoriatic symptoms, its effects on systemic inflammation and endothelial function are unknown.

In this study we want to assess the cardiovascular risks factors, endothelial dysfunction and inflammatory markers before and after treatment of moderate to severe psoriasis with an FDA approved biologic agent, adalimumab (Humira).

Official Title

Effect of Immunomodulatory Therapy With Adalimumab on Endothelial Function in Patients With Moderate to Severe Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Adalimumab 40 MG/0.8 ML Subcutaneous Solution [HUMIRA]

Other Study ID Numbers

- ABBO 0001

Study Start

2011 03

Primary Completion (Actual)

2015 03

Study Completion (Actual)

2015 03

Enrollment (Actual)

18

Study Type

Interventional

Phase

Not Applicable

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Adalimumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Adalimumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

North Carolina Locations

Chapel Hill, North Carolina, United States, 27516

UNC Dermatology Clinical Trials Unit

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Must understand and voluntarily sign an informed consent form.
- Must be male or female and age 18 55 years at time of consent.
- Must be able to adhere to the study visit schedule and other protocol requirements
- Have chronic plaque psoriasis for more than 6 months with a PASI score of 12 or greater at Baseline.
- Females of childbearing potential (FCBP)‡ must have a negative urine pregnancy test at screening (Visit 1).
- Negative PPD at Screening or 3 months earlier.
- Have not used any biologic treatment for psoriasis in the past 12 months.

Exclusion Criteria:

- Inability to provide voluntary consent
- Any condition, including the presence of laboratory abnormalities, which places the subject at unacceptable risk if he/she were to participate in the study or confounds the ability to interpret data from the study
- Pregnant, trying to become pregnant or breastfeeding
- Prior diagnosis of coronary artery disease (CAD) or heart disease.
- Systemic fungal infection
- History of past or active mycobacterial infection with any species (including Mycobacterium tuberculosis). Latent Mycobacterium tuberculosis infection as indicated by a positive (more than 15mm induration)Purified Protein Derivative [PPD] skin test. Subjects with a positive PPD skin test and documented completion of treatment for latent TB are eligible. Subjects with a positive PPD skin test and not treated or no documentation of completion of treatment are ineligible.
- History of recurrent bacterial infection (at least 3 major infections resulting in hospitalization and/or requiring intravenous antibiotic treatment within the past 2 years)
- Clinically significant abnormality on the chest x ray (CXR) at screening. Chest x rays performed within 3 months prior to start of study drug are acceptable.
- Use of any investigational medication within 4 weeks prior to start of study drug or 5 pharmacokinetic/pharmacodynamic half lives (whichever is longer)
- History of Human Immunodeficiency Virus (HIV) infection or Hepatitis C
- Positive Hepatitis B Surface antigen at screening
- Malignancy or history of malignancy (except for treated [ie, cured] basal cell skin carcinomas > 3 years prior to screening)
- History of any demyelinating disorder such as multiple sclerosis.

Ages Eligible for Study

18 Years to 55 Years (Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : N/A
Interventional Model : Single Group Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Adalimumab 40mg Adalimumab 40 MG/0.8 ML Subcutaneous Solution [HUMIRA] Dose administered every other week for 6 months	Drug: Adalimumab 40 MG/0.8 ML Subcutaneous Solution [HUMIRA] • 40mg subcutaneously, every other week for 6 months • Other Names: ◦ Humira

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage Change in Endothelial Function Compared to Baseline.	Percentage change in endothelial function between baseline visit and end of treatment, 6 months. Endothelial function was measured by percent change in brachial artery diameter after flow mediated dilation (FMD%).	6 months

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Changes in IL-6 Profile Compared to Baseline	IL6 average concentration in pg/ml at Baseline compared to end of treatment, 6 months.	6 months
Changes in Adiponectin Profile Compared to Baseline	Adiponectin concentration in pg/ml measured at Baseline and end of treatment, 6 months.	24 weeks

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

University of North Carolina, Chapel Hill

Collaborators

- AbbVie

Investigators

- Principal Investigator: Aida Lugo Somolinos, MD, University of North Carolina, Chapel Hill

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2011-03-18

First Submitted that Met QC Criteria
2011-03-18

First Posted (Estimated)
2011-03-22

Results Reporting Dates

Results First Submitted
2016-07-08

Results First Submitted that Met QC Criteria
2016-10-27

Results First Posted (Estimated)
2016-12-26

Study Record Updates

Last Update Submitted that met QC Criteria
2016-10-27

Last Update Posted (Estimated)
2016-12-26

Last Verified
2016-10

More Information

Terms related to this study

Keywords Provided by Aida Lugo-Somolinos, MD, University of North Carolina, Chapel Hill

Moderate to Severe Chronic plaque type psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Tumor Necrosis Factor Inhibitors
Anti Inflammatory Agents
Antirheumatic Agents
Adalimumab

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

IPD Plan Description

no plan to share data

Study Documents

No study documents available

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Go to the classic website

Record 1 of 1

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ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Efficacy of Secukinumab Compared to Ustekinumab in Patients With Plaque-type Psoriasis

ClinicalTrials.gov ID **NCT02074982**

Sponsor Novartis Pharmaceuticals

Information provided by Novartis (Novartis Pharmaceuticals) (Responsible Party)

Last Update Posted 2017 07 21

Study Details Tab

Study Overview

Brief Summary

This study assessed efficacy of secukinumab, compared to ustekinumab, in patients that have plaque type psoriasis

Feedback

Official Title

A 52 week, Multicenter, Randomized, Double blind Study of Subcutaneous Secukinumab to Demonstrate Efficacy as Assessed by Psoriasis Area and Severity Index at 16 Weeks of Treatment Compared to Ustekinumab and to Assess Long term Safety, Tolerability and Efficacy in Subjects With Moderate to Severe Plaque Psoriasis (CLEAR)

Conditions

Chronic Plaque Type Psoriasis

Intervention / Treatment

- Drug: AIN457 300 mg
- Drug: ustekinumab 45/90 mg
- Drug: placebo secukinumab

Other Study ID Numbers

- CAIN457A2317
- 2013 003434 32 (EudraCT Number)

Study Start (Actual)

2014 02 26

Primary Completion (Actual)

2016 06 29

Study Completion (Actual)

2016 06 29

Enrollment (Actual)

676

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Ustekinumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Ustekinumab) Secukinumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Secukinumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Alabama Locations

Birmingham, Alabama, United States, 35205
Novartis Investigative Site

Mobile, Alabama, United States, 36608
Novartis Investigative Site

Arizona Locations

Phoenix, Arizona, United States, 85032



Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- patients with moderate to severe plaque type psoriasis for at least 6 months before randomization
- patients eligible for systemic therapy with inadequately controlled psoriasis

Exclusion Criteria:

- forms of sporiasis other than plaque type psoriasis
- previous exposure to secukinumab, ustekinumab, or other biologic drugs targeting (IL) 17A or IL 17RA

Other protocol defined inclusion/exclusion criteria may apply

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: AIN457 300 mg patients received AIN457 (secukinumab) 300 mg (two secukinumab 150 mg injections) s.c. (subcutaneously) once every week at weeks 0, 1,2,3, followed by monthly dosing starting at week 4 to week 48 inclusive	Drug: AIN457 300 mg • Other Names: ◦ secukinumab
Active Comparator: Ustekinumab patients received ustekinumab 45/90 mg (weight depended, according to label) s.c. (subcutaneously) and/or placebo secukinumab injections once every week at weeks 0,1,2, and 3 followed by monthly dosing starting at week 4 to week 48 inclusive	Drug: ustekinumab 45/90 mg Drug: placebo secukinumab • Placebo

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With Moderate to Severe Plaque Psoriasis Who Achieved Psoriasis Area and Severity Index (PASI) 90 at Week 16	Psoriasis Area and Severity Index (PASI) is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72(maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 90 responders were defined as participants achieving ≥ 90% improvement at Week 16	Week 16

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Speed of Onset Based on the Percentage of Participents Achieving PASI 75 at Week 4	Psoriasis Area and Severity Index (PASI) is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72(maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity	Week 4

	parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). Speed of Onset was based on percentage PASI 75 responders and were defined as participants achieving ≥ 75% improvement at Week 4	
Percentage of Participants With Moderate to Severe Plaque Psoriasis Who Achieved Psoriasis Area and Severity Index (PASI) 90 at Week 52	Psoriasis Area and Severity Index (PASI) is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72(maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 90 responders were defined as participants achieving ≥ 90% improvement at Week 52	Week 52

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Novartis Pharmaceuticals

Collaborators

No information provided

Investigators

- Study Director: Novartis Pharmaceuticals, Novartis Pharmaceuticals

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

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Study Registration Dates

First Submitted
2014-02-27

First Submitted that Met QC Criteria
2014-02-28

First Posted (Estimated)
2014-03-03

Results Reporting Dates

Results First Submitted
2017-06-23

Results First Submitted that Met QC Criteria
2017-06-23

Results First Posted
2017-07-21

Study Record Updates

Last Update Submitted that met QC Criteria

2017-06-23

Last Update Posted

2017-07-21

Last Verified

2017-06

More Information

Terms related to this study

Keywords Provided by Novartis (Novartis Pharmaceuticals)

chronic plaque type psoriasis, secukinumab, ustekinumab, inflammatory skin disease, scaling

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Immunologic Factors
Physiological Effects of Drugs
Dermatologic Agents
Ustekinumab
Antibodies, Monoclonal

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Undecided

IPD Plan Description

Novartis is committed to sharing with qualified external researchers, access to patient level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.

This trial data availability is according to the criteria and process described on www.clinicalstudydatarequest.com

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

Yes

Studies A U.S. FDA-Regulated Device Product

No

Study Documents

No study documents available

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Record 1 of 1

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Study of Secukinumab Compared to Fumaderm® in Adults With Moderate to Severe Psoriasis. (PRIME)

ClinicalTrials.gov ID **NCT02474082**

Sponsor Novartis Pharmaceuticals

Information provided by Novartis (Novartis Pharmaceuticals) (Responsible Party)

Last Update Posted 2017 10 27

Study Details Tab

Study Overview

Brief Summary

This is a randomized, controlled, multicenter, open label study with blinded assessment of the efficacy of subcutaneous secukinumab compared to Fumaderm®, in 200 adults with moderate to severe plaque type psoriasis who are candidates for systemic therapy. The study consists of 2

Feedback

periods: a screening period of at least one week and up to four weeks, and a treatment period of 24 weeks. During the screening period eligibility of the patients is confirmed. Eligible patients are randomized 1:1 to treatment arm A or B at week 0. Patients in treatment arm A receive secukinumab administered at weeks 0, 1, 2, 3, 4, 8, 12, 16 and 20 and are followed up for assessments of the study endpoints until week 24. Patients in treatment arm B receive daily doses of Fumaderm® p.o.. Safety and efficacy measurements of secukinumab and Fumaderm® will be performed throughout the study and up to week 24.

Official Title

A Randomized, Controlled, Multicenter, Open label Study With Blinded Assessment of the Efficacy of Subcutaneous Secukinumab Compared to Fumaderm® in Adults With Moderate to Severe Plaque Psoriasis.

Conditions

Psoriasis

Intervention / Treatment

- Biological: Secukinumab
- Drug: Fumaric acid

Other Study ID Numbers

- CAIN457ADE06

Study Start

2015 04

Primary Completion (Actual)

2016 06

Study Completion (Actual)

2016 06

Enrollment (Actual)

202

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Fumaric acid (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Fumaric+acid)
Secukinumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Secukinumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Germany

- **Bad Bentheim, Germany, 48455**
  Novartis Investigative Site
- **Berlin, Germany, 10117**
  Novartis Investigative Site
- **Berlin, Germany, 10247**
  Novartis Investigative Site
- **Berlin, Germany, 10789**
  Novartis Investigative Site
- **Berlin, Germany, 13187**
  Novartis Investigative Site

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Men or women must be at least 18 years of age at the time of screening
- Chronic plaque type psoriasis diagnosed for at least 6 months before randomization Patients with moderate to severe plaque psoriasis who are candidates for systemic therapy as defined at randomization by:
- PASI score of >10
- Affected body surface area (BSA) > 10%
- DLQI >10
- Inadequate response, intolerance or contraindication to topical psoriasis treatment as documented in the patient s medical history or reported by the patient or determined by the investigator at screening.

Exclusion Criteria (abbreviated):

- Previous systemic treatment of plaque psoriasis or known contraindication for systemic therapy at baseline
- Ongoing use of other prohibited psoriasis and non psoriasis treatment.
- Clinically important active infections or infestations, chronic, recurrent or latent infections or infestations
- Patients with severe liver diseases
- Patients with severe gastrointestinal diseases including but not limited to ventricular and duodenal ulcers
- Patients with severe kidney diseases or serum creatinine above 1 x ULN
- Patients with known hematological disease or lab abnormalities
- Pregnancy, breast feeding, or unwillingness/inability to use appropriate measures of contraception (if necessary)

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Single (Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Secukinumab Patients in treatment arm A will receive a dose of 300 mg secukinumab administered as 2 subcutaneous injections of 150 mg in a SensoReady pen (i.e. 2 x 150 mg) at weeks 0, 1, 2, 3, 4, 8, 12, 16 and 20.	Biological: Secukinumab • Secukinumab 150 mg, 1 ml liquid formulation in a pre-filled pen for s.c. injection • Other Names: ◦ AIN457
Active Comparator: Fumaric acid (initial and maintenance therapy) Participants were daily self-administered with fumaric acid derivatives initial and maintenance therapy in dosetitrated scheme as per protocol. Dose was up-titrated weekly (1 tablet/day) until objective was achieved or until tapering was required or until the maximum dose of 2 tablets each at morning, noon and evening was reached,	Drug: Fumaric acid • Fumaric acid initial therapy (tablet contains 30 mg dimethylfumarate, 67 mg ethylhydrogenfumarate calcium salt, 5 mg ethylhydrogenfumarate magnesium salt, 3 mg ethylhydrogenfumarate zinc salt) and Fumaric acid maintenance therapy (tablet contains 120 mg dimethylfumarate, 87 mg ethylhydrogenfumarate calcium salt, 5 mg ethylhydrogenfumarate magnesium salt, 3 mg ethylhydrogenfumarate zinc salt) • Other Names: ◦ Fumarate, Fumaric acid, Fumaric acid esters

whichever occurred earlier.	

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Achieving Psoriasis Area and Severity Index (PASI) 75 Response at Week 24	PASI score is an average degree of severity of signs in head [H], trunk [T], upper limbs [U] and lower limbs [L], assessed separately for erythema [E], thickening (plaque elevation, induration) [I], and scaling (desquamation) [D]. Area [A] covered by lesions on each body region was estimated as a percentage (%) of total area of that particular body region and was assigned a score of 0=0%; 1=1-9%; 2=10-29%; 3=30-49%; 4=50-69%; 5=70-89%; 6=90-100%. The head and neck, upper limbs, trunk and lower limbs correspond to approximately 10%, 20%, 30% and 40% of the body surface area, respectively. PASI score was calculated as: PASI = 0.1(EH+IH+DH) AH + 0.2(EU+IU+DU) AU + 0.3(ET+IT+DT) AT + 0.4(EL+IL+DL) AL. PASI scores can range from 0 (no signs) to a maximum of 72.0. PASI 75 responders were participants who achieved >=75% improvement (reduction) in PASI score compared to baseline.	Baseline, Week 24

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Achieving Psoriasis Area	PASI score is an average degree of severity of signs in head [H], trunk [T], upper limbs [U] and lower limbs [L], assessed separately for erythema [E], thickening (plaque elevation,	Baseline, Week 1, 2, 3, 4, 6, 8, 12, 16,

and Severity Index (PASI) 50 Response at Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24	induration) [I], and scaling (desquamation) [D]. Area [A] covered by lesions on each body region was estimated as a percentage (%) of total area of that particular body region and was assigned a score of 0=0%; 1=1-9%; 2=10-29%; 3=30-49%; 4=50-69%; 5=70-89%; 6=90-100%. The head and neck, upper limbs, trunk and lower limbs correspond to approximately 10%, 20%, 30% and 40% of the body surface area, respectively. PASI score was calculated as: PASI = 0.1(EH+IH+DH) AH + 0.2(EU+IU+DU) AU + 0.3(ET+IT+DT) AT + 0.4(EL+IL+DL) AL. PASI scores can range from 0 (no signs) to a maximum of 72.0. PASI 50 responders were participants who achieved >=50% improvement (reduction) in PASI score compared to baseline.	20 and 24
Percentage of Participants Achieving Psoriasis Area and Severity Index (PASI) 75 Response at Week 1, 2, 3, 4, 6, 8, 12, 16 and 20	PASI score is an average degree of severity of signs in head [H], trunk [T], upper limbs [U] and lower limbs [L], assessed separately for erythema [E], thickening (plaque elevation, induration) [I], and scaling (desquamation) [D]. Area [A] covered by lesions on each body region was estimated as a percentage (%) of total area of that particular body region and was assigned a score of 0=0%; 1=1-9%; 2=10-29%; 3=30-49%; 4=50-69%; 5=70-89%; 6=90-100%. The head and neck, upper limbs, trunk and lower limbs correspond to approximately 10%, 20%, 30% and 40% of the body surface area, respectively. PASI score was calculated as: PASI = 0.1(EH+IH+DH) AH + 0.2(EU+IU+DU) AU + 0.3(ET+IT+DT) AT + 0.4(EL+IL+DL) AL. PASI scores can range from 0 (no signs) to a maximum of 72.0. PASI 75 responders were participants who achieved >=75% improvement (reduction) in PASI score compared to baseline.	Baseline, Week 1, 2, 3, 4, 6, 8, 12, 16 and 20
Percentage of Participants	PASI score is an average degree of severity of signs in head [H], trunk [T], upper limbs [U] and	Baseline, Week 1,

Achieving Psoriasis Area and Severity Index (PASI) 90 Response at Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24	lower limbs [L], assessed separately for erythema [E], thickening (plaque elevation, induration) [I], and scaling (desquamation) [D]. Area [A] covered by lesions on each body region was estimated as a percentage (%) of total area of that particular body region and was assigned a score of 0=0%; 1=1-9%; 2=10-29%; 3=30-49%; 4=50-69%; 5=70-89%; 6=90-100%. The head and neck, upper limbs, trunk and lower limbs correspond to approximately 10%, 20%, 30% and 40% of the body surface area, respectively. PASI score was calculated as: PASI = 0.1(EH+IH+DH) AH + 0.2(EU+IU+DU) AU + 0.3(ET+IT+DT) AT + 0.4(EL+IL+DL) AL. PASI scores can range from 0 (no signs) to a maximum of 72.0. PASI 90 responders were participants who achieved >=90% improvement (reduction) in PASI score compared to baseline.	2, 3, 4, 6, 8, 12, 16, 20 and 24
Percentage of Participants Achieving Psoriasis Area and Severity Index (PASI) 100 Response at Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24	PASI score is an average degree of severity of signs in head [H], trunk [T], upper limbs [U] and lower limbs [L], assessed separately for erythema [E], thickening (plaque elevation, induration) [I], and scaling (desquamation) [D]. Area [A] covered by lesions on each body region was estimated as a percentage (%) of total area of that particular body region and was assigned a score of 0=0%; 1=1-9%; 2=10-29%; 3=30-49%; 4=50-69%; 5=70-89%; 6=90-100%. The head and neck, upper limbs, trunk and lower limbs correspond to approximately 10%, 20%, 30% and 40% of the body surface area, respectively. PASI score was calculated as: PASI = 0.1(EH+IH+DH) AH + 0.2(EU+IU+DU) AU + 0.3(ET+IT+DT) AT + 0.4(EL+IL+DL) AL. PASI scores can range from 0 (no signs) to a maximum of 72.0. PASI 100 responders were participants who achieved complete clearance of psoriasis (PASI=0).	Baseline, Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24

Body Surface Area (BSA) at Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24	The Body surface area (BSA) affected by plaque-type psoriasis was the total of percentages of areas affected, including head, trunk, upper limbs and lower limbs. Each reported percentage was multiplied by its respective body region corresponding factor (head = 0.1, trunk = 0.3, upper limbs = 0.2, lower limbs = 0.4). The resulting four percentages were added to estimate the total BSA affected by plaque-type psoriasis.	Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24
Percentage of Participants Achieving Nail Psoriasis Severity Index (NAPSI) 50 Response at Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24	NAPSI was used to assess psoriatic nail involvement in participants with nail psoriasis. NAPSI score was calculated as total of nail matrix and nail bed score, ranging from 0-8 per nail. Total NAPSI score ranges from 0 to 80 for all fingernails. Each nail was divided with imaginary horizontal and longitudinal lines into quadrants. Each nail was given a score of 0 - 4 for nail matrix and nail bed psoriasis 0-4 (0: for none, 1: for 1 quadrant, 2: for 2 quadrants, 3: for 3 quadrants, 4: for all 4 quadrants), based on presence of any feature of nail psoriasis in that quadrant. Nail matrix psoriasis feature includes: pitting, leukonychia red spots in lunula, crumbling. Nail bed psoriasis feature includes: onycholysis, splinter hemorrhages, subungual hyperkeratosis, "oil drop" (salmon patch dyschroma). NPASI 50 responders were participants who achieved >=50% improvement (reduction) in NPASI score compared to baseline.	Baseline, Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24
Percentage of Participants Achieving Nail Psoriasis Severity Index (NAPSI) 75 Response at	NAPSI was used to assess psoriatic nail involvement in participants with nail psoriasis. NAPSI score was calculated as total of nail matrix and nail bed score, ranging from 0-8 per nail. Total NAPSI score ranges from 0 to 80 for all fingernails. Each nail was divided with imaginary horizontal and longitudinal lines into	Baseline, Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24

Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24	quadrants. Each nail was given a score of 0 - 4 for nail matrix and nail bed psoriasis 0-4 (0: for none, 1: for 1 quadrant, 2: for 2 quadrants, 3: for 3 quadrants, 4: for all 4 quadrants), based on presence of any feature of nail psoriasis in that quadrant. Nail matrix psoriasis feature includes: pitting, leukonychia red spots in lunula, crumbling. Nail bed psoriasis feature includes: onycholysis, splinter hemorrhages, subungual hyperkeratosis, "oil drop" (salmon patch dyschroma). NPASI 75 responders were participants who achieved >=75% improvement (reduction) in NPASI score compared to baseline.	
Percentage of Participants Achieving Nail Psoriasis Severity Index (NAPSI) 90 Response at Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24	NAPSI was used to assess psoriatic nail involvement in participants with nail psoriasis. NAPSI score was calculated as total of nail matrix and nail bed score, ranging from 0-8 per nail. Total NAPSI score ranges from 0 to 80 for all fingernails. Each nail was divided with imaginary horizontal and longitudinal lines into quadrants. Each nail was given a score of 0 - 4 for nail matrix and nail bed psoriasis 0-4 (0: for none, 1: for 1 quadrant, 2: for 2 quadrants, 3: for 3 quadrants, 4: for all 4 quadrants), based on presence of any feature of nail psoriasis in that quadrant. Nail matrix psoriasis feature includes: pitting, leukonychia red spots in lunula, crumbling. Nail bed psoriasis feature includes: onycholysis, splinter hemorrhages, subungual hyperkeratosis, "oil drop" (salmon patch dyschroma). NPASI 90 responders were participants who achieved >=90% improvement (reduction) in NPASI score compared to baseline.	Baseline, Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24
Percentage of Participants Achieving Nail	NAPSI was used to assess psoriatic nail involvement in participants with nail psoriasis. NAPSI score was calculated as total of nail	Baseline, Week 1, 2, 3, 4, 6,

Psoriasis Severity Index (NAPSI) 100 Response at Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24	matrix and nail bed score, ranging from 0-8 per nail. Total NAPSI score ranges from 0 to 80 for all fingernails. Each nail was divided with imaginary horizontal and longitudinal lines into quadrants. Each nail was given a score of 0 - 4 for nail matrix and nail bed psoriasis 0-4 (0: for none, 1: for 1 quadrant, 2: for 2 quadrants, 3: for 3 quadrants, 4: for all 4 quadrants), based on presence of any feature of nail psoriasis in that quadrant. Nail matrix psoriasis feature includes: pitting, leukonychia red spots in lunula, crumbling. Nail bed psoriasis feature includes: onycholysis, splinter hemorrhages, subungual hyperkeratosis, "oil drop" (salmon patch dyschroma). NPASI 100 responders were participants who PASI 100 responders were participants who achieved complete clearance of psoriasis.	8, 12, 16, 20 and 24
Number of Participants With Investigator s Global Assessment (IGA Mod 2011) at Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24	IGA mod 2011 is a global static severity rating scale referring exclusively to the participant s disease state at the time of the assessments and don t attempt comparison with participant s any previous disease states at baseline or visit. IGA mod 2011 has a scale of 0-4 with the lower scores correlating to better performance. Scores used were: 0/Clear: no signs of psoriasis, Post-inflammatory hyperpigmentation may be present; 1/almost clear: Normal to pink coloration of lesions/no thickening/no to minimal focal scaling; 2/Mild: Pink to light red coloration/just detectable to mild thickening/predominantly fine scaling; 3/Moderate: Dull bright red, clearly distinguishable erythema/clearly distinguishable to moderate thickening/moderate scaling; 4/Severe: Bright to deep dark red coloration/severe thickening with hard edges/severe or coarse scaling covering almost all or all lesions.	Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24

Percentage of Participants With IGA Mod. 2011 0/1-response at Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24	The IGA mod 2011 scale has been developed based on a previous version of the scale used in secukinumab phase II studies in collaboration with health authorities, in particular the FDA. The explanations/descriptions of the points on the scale have been improved to ensure appropriate differentiation between the points. The IGA mod 2011 used in this study is static, i.e. it refers exclusively to the subject s disease state at the time of the assessments, and does not attempt a comparison with any of the subject s previous disease states, whether at baseline or at a previous visit.IGA mod 2011 has a scale of 0-4 with the lower scores correlating to better performance. A score of 0= clear skin, 1= almost clear skin, 2=mild, 3=moderate,4=severe. IGA 0/1 responders: who achieved score of 0/1 and improved by at least 2 points on the IGA scale compared to baseline.	Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24
Dermatology Life Quality Index (DLQI) at Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24	DLQI is a 10-item general dermatology disability index designed to assess health-related quality of life in adult subjects with skin diseases such as eczema, psoriasis, acne, and viral. The measure was self-administered and included domains of daily activities, leisure, personal relationships, symptoms and feelings, treatment, and work/school. Each item had four response categories ranging from 0 (not at all) to 3 (very much). "Not relevant" was also a valid response and was scored as 0. The DLQI total score was a sum of the 10 questions. Scores ranged from 0 to 30, with higher scores indicating greater impairment in health related quality of life.	Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24

Percentage of Participants With DLQI 0/1 Response at Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24	DLQI is a 10-item general dermatology disability index designed to assess health-related quality of life in adult subjects with skin diseases such as eczema, psoriasis, acne, and viral. The measure was self-administered and included domains of daily activities, leisure, personal relationships, symptoms and feelings, treatment, and work/school. Each item had four response categories ranging from 0 (not at all) to 3 (very much). "Not relevant" was also a valid response and was scored as 0. The DLQI total score was a sum of the 10 questions. Scores ranged from 0 to 30, with higher scores indicating greater impairment in health related quality of life. DLQI 0/1 response was the achievement of a DLQI score of 0 or 1.	Week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24
Percentage of Participants With Short Form 36 (SF-36) Response at Week 4, 16 and 24	SF-36 is a generic indicator of health status for use in population surveys and evaluative studies of health policy. The SF-36 included 36 items in a Likert-type or forced-choice format measured on eight dimensions. The scores for each domain range from 0 to 100, with high scores indicating a better status. SF-36 responder is defined as subject reaching at least an improvement of minimum important difference (MID). The SF-36 measure dimensions and their MID includes: • Physical Functioning:4.3 • Role-Physical: 3.4 • Bodily Pain: 6.2 • General Health: 7.2 • Vitality: 6.2 • Social Functioning: 6.9 • Role-Emotional: 4.5 • Mental Health: 6.2 Two component scores and their MID which were derived from the above mentioned 8 domains includes-:	Week 4, 16 and 24

- Physical component summary: 3.4
- Mental component summary: 4.6

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Novartis Pharmaceuticals

Collaborators

No information provided

Investigators

No information provided

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2015-04-16

First Submitted that Met QC Criteria
2015-06-16

First Posted (Estimated)
2015-06-17

Results Reporting Dates

Results First Submitted
2017-06-11

Results First Submitted that Met QC Criteria
2017-06-11

Results First Posted
2017-10-27

Study Record Updates

Last Update Submitted that met QC Criteria
2017-06-11

Last Update Posted
2017-10-27

Last Verified
2017-06

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

The Efficacy and Safety of Adding Methotrexate to Etanercept in Psoriasis

ClinicalTrials.gov ID **NCT01001208**

Sponsor Amgen

Information provided by Amgen (Responsible Party)

Last Update Posted 2013 08 12

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to evaluate the efficacy of adding methotrexate to etanercept compared with etanercept monotherapy as measured by the percentage of participants achieving a 75% improvement from baseline in the Psoriasis Area and Severity Index (PASI 75) at Week 24.

Feedback

Official Title

A Randomized, Double Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Adding Methotrexate to Etanercept in Subjects With Moderate to Severe Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Methotrexate
- Drug: Etanercept
- Drug: Placebo

Other Study ID Numbers

- 20070559

Study Start

2009 11

Primary Completion (Actual)

2010 12

Study Completion (Actual)

2011 02

Enrollment (Actual)

478

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Methotrexate (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Methotrexate)

Etanercept (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Etanercept)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

No location data

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person s general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Is capable of understanding and giving written, voluntary informed consent before study screening
- Male or female ≥18 years of age at time of screening
- Has had stable moderate to severe plaque psoriasis for at least 6 months (eg, no morphology changes or significant flares of disease activity)
- Has involved body surface area (BSA) ≥ 10% and Psoriasis Area and Severity Index (PASI) ≥ 10 at screening and at baseline
- Is a candidate for systemic therapy or phototherapy in the opinion of the investigator
- Has a negative test for hepatitis B surface antigen and hepatitis C antibody
- Has a negative purified protein derivative test within 30 days prior to the first IP dose. Tuberculin skin tests should be considered positive when they have greater than or equal to 5 mm of induration at 48 72 hours after test is placed. Patients with a positive tuberculin skin test (if less than or equal to 14 mm of induration) are allowed if they have a history of Bacillus Calmette Guerin vaccination with a negative Quantiferon test in the past year, no symptoms per tuberculosis worksheet, and a negative chest X ray.
- Has a negative serum pregnancy test within 28 days before initiating Investigational Product (IP) and negative urine pregnancy test at baseline for females (except those at least 3 years post menopausal or surgically sterile)
- Females are willing to use highly effective form of birth control (decided upon with the investigator) during the study and for 3 months after the end of treatment (except women at least 3 years post menopausal or surgically sterile)
- Males are willing to use highly effective form of birth control (decided upon with the investigator) during the study and for 5 months after the end of treatment (except for men who are surgically sterile or whose female partners are at least 3 years post menopausal, surgically sterile, or are using a highly effective form of birth control)
- Men with a pregnant female partner are willing to use effective methods (decided upon with the investigator) to ensure that an unborn child is not exposed to IP via semen
- Patient or designee must have the ability to inject etanercept subcutaneously

Exclusion Criteria:

Skin disease related

- Has active guttate, erythrodermic, or pustular psoriasis at the time of the screening visit.
- Has evidence of skin conditions at the time of the screening visit (eg, eczema) that would interfere with evaluations of the effect of IP on psoriasis.

Medical conditions

- Has significant concurrent medical conditions, including:
- Type 1 diabetes
- Poorly controlled type 2 diabetes (hemoglobin A1c > 8.5)
- Symptomatic heart failure (New York Heart Association [NYHA] class II, III, or IV)

- Myocardial infarction within the last year
- Current or history of unstable angina pectoris within the last year
- Uncontrolled hypertension as defined by a resting blood pressure ≥ 160/95 mmHg prior to randomization (confirmed by a repeat assessment)
- Severe chronic pulmonary disease (eg, requiring oxygen therapy)
- No major chronic inflammatory disease or connective tissue disease other than psoriasis and/or psoriatic arthritis
- Multiple sclerosis or any other demyelinating disease
- Active malignancy, including evidence of cutaneous basal or squamous cell carcinoma or melanoma, or history of cancer (other than fully resected and surgically cured cutaneous basal cell and squamous cell carcinoma) within 5 years before the first IP dose. If malignancy occurred more than 5 years ago, documentation of disease free state since treatment is required.
- Known immunodeficiency syndromes including human immunodeficiency virus (HIV)
- Uncontrolled, clinically significant history of renal disease
- Alcoholic hepatitis
- Any condition that, in the opinion of the investigator, might cause this study to be detrimental to the patient
- Has any active CTC grade 2 or higher infection (including chronic or localized infections) within 30 days prior to screening, at screening, or during screening period prior to first investigational product (IP) dose
- Is pregnant or breast feeding
- Has any condition that could, in the opinion of the investigator, compromise the patient s ability to give written consent and/or comply with the study procedures, such as a history of substance abuse or a psychiatric condition Methotrexate contraindications or precautions
- Has a family history of heritable liver disease (eg, hemachromatosis, Wilson s disease)
- Has a history of or evidence at screening or baseline of alcohol abuse, alcoholic liver disease, or other clinically significant liver disease
- Is unwilling or unable to limit alcohol consumption during the 24 week trial period (allowable limits are: not more than 4 drinks a week, not more than 2 drinks in a single day. 1 drink = 1 (5 oz) glass of wine = 1.5 oz liquor = 12 oz of beer or hard cider)
- Has an estimated total cumulative methotrexate exposure (by medical history) exceeding 1000 mg, unless a subsequent liver biopsy has demonstrated no grade IIIb or greater injury
- Has a history of significant methotrexate toxicity including pneumonitis or significant cytopenias

Laboratory abnormalities

- Has laboratory abnormalities at screening, including:
- Aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT) > the upper limit of normal (if screen fail for abnormal AST/ALT, 1 repeat measurement is allowed)
- Serum total bilirubin ≥ 1.5 mg/dL
- Abnormal serum albumin (< 3.5 g/dL)
- Hemoglobin < 11 g/dL

- Platelet count < 125,000 /mm^3
- White blood cell count < 3,500 cells/mm^3
- Absolute neutrophil count < 1500/mm^3
- Estimated creatinine clearance < 50 mL/min (Cockroft Gault formula, calculated value to be provided to sites)
- Any other laboratory abnormality, which, in the opinion of the investigator, will prevent the patient from completing the study or will interfere with the interpretation of the study results

Washouts and disallowed medications

- Has used any of the following therapies within 14 days of IP initiation:
- Ultraviolet light B therapy
- Topical cyclosporine or calcineurin inhibitors
- Topical vitamin A or D analog preparations
- Class III through VII topical steroids (exception: permitted on the scalp, axillae, and groin)
- Has used any of the following therapies within 28 days of IP initiation:
- Intravenous or oral calcineurin inhibitors
- Ultraviolet light A therapy
- Psoralen and ultraviolet light A therapy
- Oral retinoids
- Class I or II topical steroids
- Anthralin
- Any other systemic psoriasis therapy (eg, cyclosporine), including oral or parenteral corticosteroids
- Cyclophosphamide
- Sulfasalazine
- Has used methotrexate within 28 days of IP initiation. Patients with prior use of methotrexate must be excluded if subject discontinued because of a clinically significant adverse event (eg, severe skin reactions, methotrexate induced lung disease, or any other adverse event that the investigator feels might cause this study to be detrimental to the patient)
- Has used biologic therapies (other than interleukin (IL)12/IL23 inhibitors or anti timor necrosis factor (TNF) agents) within 3 months of IP initiation
- Has used an IL12/23 inhibitor within 6 months of IP initiation (eg, CNTO 1275, ABT 874)
- Has used one or more anti TNF agents (eg, etanercept, adalimumab, infliximab) within 3 months of IP initiation. Patients with prior use of an anti TNF agent must be excluded if the subject discontinued for lack of efficacy or a clinically significant adverse event (eg, serious infection, neurologic event, malignancy, hematologic event, or any other adverse event that the investigator feels might cause this study to be detrimental to the patient).
- Has previously used efalizumab (Raptiva®).
- Other investigational procedures are excluded.
- currently enrolled in or has not yet completed at least 30 days or 5 half lives (if applicable; whichever is longer) since ending other investigational device or drug study(s), or is receiving other investigational agent(s).

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Triple (Participant, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Etanercept Plus Methotrexate Participants received 50 mg etanercept twice weekly (BIW) for the first 12 weeks and then 50 mg etanercept once weekly (QW) for the second 12 weeks. Participants also received active methotrexate titrated as follows: 7.5 mg per week (3 capsules) for weeks 1 and 2, 10 mg per week (4 capsules) for weeks 3 and 4, and then up to 15 mg per week (6 capsules) or the maximum tolerated dose for the remainder of the 24-week treatment period.	Drug: Methotrexate • Methotrexate tablets over-encapsulated for blinding Drug: Etanercept • 1 mL for subcutaneous injection • Other Names: ◦ Enbrel

Active Comparator: Etanercept Plus Placebo Participants received 50 mg etanercept twice weekly (BIW) for the first 12 weeks and then 50 mg etanercept once weekly (QW) for the second 12 weeks. Participants also received oral placebo that was the same number of capsules per week as the methotrexate dosing regimen.	Drug: Etanercept • 1 mL for subcutaneous injection • Other Names: ◦ Enbrel Drug: Placebo • Matching placebo to methotrexate capsules

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
PASI 75 Response at Week 24	Percentage of participants achieving at least a 75% decrease (improvement) from Baseline in the Psoriasis Area and Severity Index (PASI) at Week 24. PASI Score incorporates measures of erythema, desquamation, infiltration, and affected body surface area. Involvement and severity of psoriasis was scored by a blinded assessor using a scale of 0 to 72, where 0 = no psoriasis and 72 = severe disease.	Baseline and 24 Weeks

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame

PASI 50 Response at Week 24	Percentage of participants achieving at least a 50% decrease (improvement) from Baseline in the Psoriasis Area and Severity Index (PASI) at Week 24. PASI Score incorporates measures of erythema, desquamation, infiltration, and affected body surface area. Involvement and severity of psoriasis was scored by a blinded assessor using a scale of 0 to 72, where 0 = no psoriasis and 72 = severe disease.	Baseline and 24 Weeks
Static Physician Global Assessment (sPGA) Response at Week 24	Percentage of participants achieving a clear (0) or almost clear (1) status on the Static Physician Global Assessment (sPGA) at Week 24. This index evaluates the physician s global assessment of the participant s psoriasis based on severity of induration, scaling, and erythema. The assessment was scored by a blinded assessor on a scale of 0 to 5, where 0 = clear, with no evidence of plaque elevation, erythema, or scale, and 5 = severe induration, erythema, and scaling.	Week 24
PASI 50 Response at Week 12	Percentage of participants achieving at least a 50% decrease (improvement) from Baseline in the Psoriasis Area and Severity Index (PASI) at Week 12. PASI Score incorporates measures of erythema, desquamation, infiltration, and affected body surface area. Involvement and severity of psoriasis was scored by a blinded assessor using a scale of 0 to 72, where 0 = no psoriasis and 72 = severe disease.	Baseline and 12 Weeks
PASI 75 Response at Week 12	Percentage of participants achieving at least a 75% decrease (i.e. improvement) from Baseline in the Psoriasis Area and Severity Index (PASI) at Week 12. PASI Score incorporates measures of erythema, desquamation, infiltration, and affected body surface area. Involvement and severity of psoriasis was scored by a blinded	Baseline and 12 Weeks

	assessor using a scale of 0 to 72, where 0 = no psoriasis and 72 = severe disease.	
Static Physician Global Assessment (sPGA) Response at Week 12	Percentage of participants achieving a clear (0) or almost clear (1) status on the Static Physician Global Assessment (sPGA) at Week 12. This index evaluates the physician s global assessment of the participant s psoriasis based on severity of induration, scaling, and erythema. The assessment was scored by a blinded assessor on a scale of 0 to 5, where 0 = clear, with no evidence of plaque elevation, erythema, or scale, and 5 = severe induration, erythema, and scaling.	Week 12
PASI 90 Response at Week 12	Percentage of participants achieving at least a 90% decrease (improvement) from Baseline in the Psoriasis Area and Severity Index (PASI) at Week 12. PASI Score incorporates measures of erythema, desquamation, infiltration, and affected body surface area. Involvement and severity of psoriasis was scored by a blinded assessor using a scale of 0 to 72, where 0 = no psoriasis and 72 = severe disease.	Baseline and 12 Weeks
PASI 90 Response at Week 24	Percentage of participants achieving at least a 90% decrese (improvement) from Baseline in the Psoriasis Area and Severity Index (PASI) at Week 24. PASI Score incorporates measures of erythema, desquamation, infiltration, and affected body surface area. Involvement and severity of psoriasis was scored by a blinded assessor using a scale of 0 to 72, where 0 = no psoriasis and 72 = severe disease.	Baseline and 24 Weeks
Change From Baseline in the Percentage of Body Surface Area Involved	A measurement of psoriasis involvement, given as the physician s assessment of the percentage of the participant s total body surface area (BSA) involved with psoriasis. The BSA numerical score was completed by a blinded assessor. A	Baseline and 12 Weeks

With Psoriasis at Week 12	decrease from Baseline indicates improvement. Change from Baseline was calculated as Baseline score - Week 12 score; a positive change from Baseline therefore indicates improvement.	
Change Form Baseline in Percentage of Body Surface Area Involved With Psoriasis at Week 24	A measurement of psoriasis involvement, given as the physician s assessment of the percentage of the participant s total body surface area (BSA) involved with psoriasis. The BSA numerical score was completed by a blinded assessor. A decrease from Baseline indicates improvement. Change from Baseline was calculated as Baseline score - Week 24 score; a positive change from Baseline therefore indicates improvement.	Baseline and 24 Weeks

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Amgen

Collaborators

- Immunex Corporation

Investigators

- Study Director: MD, Amgen

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2009-10-15

First Submitted that Met QC Criteria
2009-10-22

First Posted (Estimated)
2009-10-26

Results Reporting Dates

Results First Submitted
2011-12-21

Results First Submitted that Met QC Criteria
2013-07-10

Results First Posted (Estimated)
2013-08-12

Study Record Updates

Last Update Submitted that met QC Criteria
2013-07-10

Last Update Posted (Estimated)
2013-08-12

Last Verified

2013-07

More Information

Terms related to this study

Keywords Provided by Amgen

Etanercept
Methotrexate
Psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Abortifacient Agents, Nonsteroidal
Abortifacient Agents
Reproductive Control Agents
Physiological Effects of Drugs
Antimetabolites, Antineoplastic
Antimetabolites
Molecular Mechanisms of Pharmacological Action
Antineoplastic Agents
Dermatologic Agents
Enzyme Inhibitors
Folic Acid Antagonists
Immunosuppressive Agents
Immunologic Factors
Antirheumatic Agents
Nucleic Acid Synthesis Inhibitors
Anti Inflammatory Agents, Non Steroidal
Analgesics, Non Narcotic
Analgesics
Sensory System Agents
Peripheral Nervous System Agents
Anti Inflammatory Agents
Gastrointestinal Agents
Etanercept
Methotrexate

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by Amgen

AmgenTrials clinical trials website (http://www.amgentrials.com)

C n ca Tr a s gov return to the CTG homepage

Go to the c ass c webs te

Record 1 of 1

The U.S. government does not review or approve the safety and science of all studies listed on this website.

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C n ca Tr a s gov s a webs te and on ne database of c n ca research stud es and nformat on about the r resu ts The Nat ona L brary of Med c ne (NLM) ma nta ns the webs te **The study sponsor or investigator submits information** about the r study to C n ca Tr a s gov and **is responsible for the safety, science, and accuracy** of any study they st

Before jo n ng a study, ta k to your hea th care profess ona about poss b e r sks and benefits To earn more about tak ng part n stud es, read Learn About Stud es (https //c n ca tr a s gov/study bas cs/ earn about stud es)

COMPLETED

Observational Study Evaluating Etanercept (Enbrel®) In Subjects With Plaque-Type Psoriasis In Usual Care Settings

ClinicalTrials.gov ID NCT00708708

Sponsor Pfizer

Information provided by Pfizer (Respons b e Party)

Last Update Posted 2015 07 27

Study Details Tab

Study Overview

Brief Summary

Th s prospect ve observat ona cohort study w assess the average durat on of the drug free nterva between etanercept treatment cyc es n usua care sett ngs n Germany

Detailed Description

Non ntervent ona study subjects to be se ected accord ng to the usua c n ca pract ce of the r phys c an

Official Title

A Prospect ve Non ntervent ona Study (N s) Of The Rout ne Use Of Etanercept n The Long term Treatment Of Pat ents W th P aque type Psor as s n Everyday Pract ce An Efficacy, Safety, And Hea th Econom c Eva uat on

Conditions

Psor as s

Intervention / Treatment

- Drug etanercept (Enbre ®)

Other Study ID Numbers

- 0881X1 4499
- B1801081 (Other dent fier) (OTHER A as Study Number)

Feedback

Study Start

2008 06

Primary Completion (Actual)

2013 12

Study Completion (Actual)

2013 12

Enrollment (Actual)

926

Study Type

Observat ona

Resource links provided by the National Library of Medicine

Med neP us (https //med nep us gov/) re ated top cs Psor as s (https //med nep us gov/psor as s htm)

Drug nformat on (https //da ymed n m n h gov/da ymed/) ava ab e for Etanercept (https //da ymed n m n h gov/da ymed/search cfm? abe type=human&query=Etanercept)

Other U S FDA Resources (https //c ass c c n ca tr a s gov/ct2/ nfo/fda nks)

Contacts and Locations

Th s sect on prov des the contact deta s for those conduct ng the study, and nformat on on where th s study s be ng conducted

Germany

NRW Locations

Muenster, NRW, Germany, 48149
Wes faelische Wilhelms Universi ae Muens er, Zen r f Derm

C ck to v ew nteract ve map

Participation Criteria

Researchers ook for peop e who fit a certa n descr pt on, ca ed e g b ty cr ter a Some examp es of these cr ter a are a person's genera hea th cond t on or pr or treatments

For genera nformat on about c n ca research, read Learn About Stud es (https //c n ca tr a s gov/study bas cs/ earn about stud es)

Eligibility Criteria

Description

nc us on Cr ter a

- Subjects w th moderate to severe p aque psor as s on etanercept treatment accord ng to the Summary of Product Character st cs (SmPC), and app cab e oca gu de nes
- Subjects for whom the dec s on has a ready been made to n t ate treatment w th etanercept

Exc us on Cr ter a

- Seps s or r sk of seps s
- Current or recent nfect ons, nc ud ng chron c or oca zed, e g tubercu os s (TB) nfect on
- Vacc nat on w th ve vacc ne n ast 4 weeks, or expected to requ re such vacc nat on dur ng the course of the study
- Pre ex st ng or recent onset CNS demye nat ng d sease
- C ass or V congest ve heart fa ure as defined by the New York Heart Assoc at on c ass ficat on or uncompensated congest ve heart fa ure
- Prev ous or ongo ng treatment w th etanercept
- Part c pat on n other c n ca or observat ona stud es
- Pat ents w th psor at c arthr t s requ r ng cont nuous etanercept treatment

Study Population

Pat ents w th moderate to severe p aque psor as s

Ages Eligible for Study

18 Years and o der (Adu t, O der Adu t)

Sexes Eligible for Study

A

Accepts Healthy Volunteers

No

Sampling Method

Non Probab ty Samp e

Study Plan

Th s sect on prov des deta s of the study p an, nc ud ng how the study s des gned and what the study s measur ng

How is the study designed?

Design Details

Observational Model : Cohort
Time Perspective: Prospect ve

Cohorts and Interventions

Group/Cohort	Intervention/Treatment
A Pat ents w th moderate to severe p aque psor as s	Drug etanercept (Enbre ®) • The pat ents w be treated n accordance w th the requ rements of the abe ng of etanercept n Germany The dosage and durat on of therapy s to be determ ned by the phys c an to meet the pat ents' nd v dua needs for treatment

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Durat on of Drug-Free nterva Pr or to Treatment Cyc e 2	Average durat on of part c pant's drug-free nterva between the end of treatment Cyc e 1 and Cyc e 2 was reported n weeks Durat on of drug-free nterva was computed as (date of start of new treatment cyc e m nus date of ast app cat on of etanercept pr or to drug free nterva p us 1) d v ded by 7 and t was determ ned for on y those part c pants who had nformat on ava ab e regard ng drug-free nterva	Cyc e 1 Week 24 up to Cyc e 2 Week 0
Durat on of Drug-Free nterva Pr or to Treatment Cyc e 3	Average durat on of part c pant's drug-free nterva between the end of treatment Cyc e 2 and Cyc e 3 was reported n weeks Durat on of drug-free nterva was computed as (date of start of new treatment cyc e m nus date of ast app cat on of etanercept pr or to drug free nterva p us 1) d v ded by 7 and t was determ ned for on y those part c pants who had nformat on ava ab e regard ng drug-free nterva	Cyc e 2 Week 24 up to Cyc e 3 Week 0
Durat on of Drug-Free nterva Pr or to Treatment Cyc e 4	Average durat on of part c pant's drug-free nterva between the end of treatment Cyc e 3 and Cyc e 4 was reported n weeks Durat on of drug-free nterva was computed as (date of start of new treatment cyc e m nus date of ast app cat on of etanercept pr or to drug free nterva p us 1) d v ded by 7 and t was determ ned for on y those part c pants who had nformat on ava ab e regard ng drug-free nterva	Cyc e 3 Week 24 up to Cyc e 4 Week 0
Durat on of Drug-Free nterva Pr or to Treatment Cyc e 5	Average durat on of part c pant's drug-free nterva between the end of treatment Cyc e 4 and Cyc e 5 was reported n weeks Durat on of drug-free nterva was computed as (date of start of new treatment cyc e m nus date of ast app cat on of etanercept pr or to drug free nterva p us 1) d v ded by 7 and t was determ ned for on y those part c pants who had nformat on ava ab e regard ng drug-free nterva	Cyc e 4 Week 24 up to Cyc e 5 Week 0
Durat on of Drug-Free nterva Pr or to Treatment Cyc e 6	Average durat on of part c pant's drug-free nterva between the end of treatment Cyc e 5 and Cyc e 6 was reported n weeks Durat on of drug-free nterva was computed as (date of start of new treatment cyc e m nus date of ast app cat on of etanercept pr or to drug free nterva p us 1) d v ded by 7 and t was determ ned for on y those part c pants who had nformat on ava ab e regard ng drug-free nterva	Cyc e 5 Week 24 up to Cyc e 6 Week 0

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Psor as s Area and Sever ty ndex (PAS) Score	Comb ned assessment of es on sever ty and area affected nto s ng e score Body was d v ded nto 4 sect ons head, arms, trunk, egs For each sect on, percent (%) area of sk n nvo ved was est mated 0= 0% to 6= 90-100% Sever ty was est mated by c n ca s gns erythema, ndurat on, desquamat on; sca e 0= none to 4= max mum F na PAS = sum of sever ty parameters for each sect on*area score*we ght of sect on (head 0 1, arms 0 2, body 0 3, egs 0 4); tota poss b e score range 0= no d sease to 72= max ma d sease PAS score at Week 0 of each cyc e s gn fies the d sease act v ty at the t me of resumpt on of etanercept therapy	Week 0, 12, 24 of Cyc e 1 to 6
Percentage of Body Surface Area (BSA) Affected by Psor as s	Percentage of body surface area affected by psor as s was est mated us ng the pa m method one of the part c pant's pa m to prox ma nterpha angea and thumb = 1% of tota BSA Reg ons of the body were ass gned spec fic number of pa ms w th percentage [Head and neck = 10% (10 pa ms), upper extrem t es = 20% (20 pa ms), Trunk (ax ae and gro n) = 30% (30 pa ms), ower extrem t es (buttocks) = 40% (40 pa ms)] The tota BSA affected was the summat on of nd v dua reg ons affected The resu ts of th s outcome measure was summar zed separate y for part c pants w thout drug-free nterva , part c pants w th drug-free nterva and rema n ng part c pants, as per p anned ana ys s	Week 0, 12, 24 of Cyc e 1 to 6
Stat c Phys c an G oba Assessment (sPGA) of D sease Act v ty	Stat c phys c an g oba assessment (sPGA) of d sease act v ty was assessed as 0 (no psor as s) to 5 (severe d sease) based on sever ty of ndurat on, sca ng, and erythema across a psor at c es ons	Week 0, 12, 24 of Cyc e 1 to 6
Phys c an G oba Assessment of Efficacy	Phys c an assessed the effect veness of etanercept treatment at the end (Week 24) of each cyc e as very good, good, moderate, and nsuffic ent	Week 24 of Cyc e 1 to 6
Pat ent G oba Assessment of Efficacy	Part c pant assessed the effect veness of etanercept treatment at the end (Week 24) of each cyc e as very good, good, moderate, and nsuffic ent	Week 24 of Cyc e 1 to 6
Number of nject ons Per Year	Number of etanercept nject ons per year were ca cu ated up to 5 years 'By year' ana ys s was not poss b e for those part c pants for whom the data of one or more v s ts was m ss ng	Year 1, 2, 3, 4, 5
Cumu at ve Dose of Etanercept Per Year	Cumu at ve dose of etanercept per year was ca cu ated up to 5 years 'By year' ana ys s was not poss b e for those part c pants for whom the data of one or more v s ts was m ss ng	Year 1, 2, 3, 4, 5
Percentage of T me on Treatment n F rst Year	Percentage of t me on etanercept treatment for first year was ca cu ated t was ca cu ated as 100% * (365- sum of durat ons of drug-free nterva s n the first year)/365 Ana ys s was not poss b e for part c pants w th m ss ng data of v s t 1 (Week 0) of Cyc e 1	Year 1
Percentage of T me on Treatment Over Ent re	Percentage of t me on etanercept treatment over ent re treatment per od was ca cu ated t was ca cu ated as 100% * ([Date of ast app cat on -	Cyc e 1 up to Cyc e 6

Per od	Date of first app cat on + 1] - Sum of durat on of drug-free nterva s [days])/(Date of ast app cat on - Date of first app cat on + 1)	
Pat ent's G oba Assessment of D sease Act v ty (PatGA)	Part c pants were asked to rate the sever ty of the r d sease act v ty on a 6-po nt sca e, where 0 = no act v ty and 5 = severe or max mum act v ty	Week 0, 12, 24 of Cyc e 1 to 6
Dermato ogy L fe Qua ty ndex (DLQ) Score	DLQ s the dermato ogy-spec fic qua ty of fe measure used for psor at c popu at on The 10- tem quest onna re has a score range of 0 to 30 w th h gher scores nd cat ng poor qua ty of fe An est mate of the m n ma c n ca y mportant d fference of the DLQ tota score s a 5 po nt mprovement Tota score range 0 (best) to 30 (worst)	Week 0, 12, 24 of Cyc e 1 to 6
Euro Qua ty of L fe-5 D mens ons (EQ-5D) T me Trade Off (TTO)	EQ-5D part c pant rated quest onna re to assess hea th-re ated qua ty of fe Hea th State Profi e component assesses eve of current hea th for 5 doma ns mob ty, se f-care, usua act v t es, pa n and d scomfort, and anx ety and depress on; 1 nd cates better hea th state (no prob ems); 3 nd cates worst hea th state (extreme prob ems) Score of each doma n s transformed nto a s ng e TTO va ue us ng formu a deve oped by Gre ner et a and resu ts n a tota score range -0 205 to 0 999; h gher score nd cates a better hea th state	Week 0, 12, 24 of Cyc e 1 to 6
Euro Qua ty of L fe (EQ-5D)- V sua Ana og Sca e (VAS)	EQ-5D part c pant rated quest onna re to assess hea th-re ated qua ty of fe Hea th State Profi e component assesses eve of current hea th for 5 doma ns mob ty, se f-care, usua act v t es, pa n and d scomfort, and anx ety and depress on; 1 nd cates better hea th state (no prob ems); 3 nd cates worst hea th state Score of each doma n s transformed nto a s ng e VAS score us ng formu a deve oped by Gre ner et a and resu ts n a tota score range of 0 to 100, where h gher score nd cates a better hea th state	Week 0, 12, 24 of Cyc e 1 to 6
Number of Part c pants W th at Least 1 Concom tant Med cat on	Number of part c pants tak ng any non-study med cat ons wh ch were adm n stered dur ng the per od of etanercept treatment for the management of an adverse event or for the treatment of any other d sease and not p aque psor as s were reported	Cyc e 1 Week 0 up to Cyc e 6 Week 24
Annua Costs for Treatment W th Etanercept	Costs for treatment w th etanercept per year up to 5 years was ca cu ated n Euros 'By year' ana ys s was not poss b e for those part c pants for whom the data of 1 or more v s ts was m ss ng	Year 1, 2, 3, 4, 5
Average Cost of Treatment by D sease Sever ty	Average costs for treatment w th etanercept up to 5 years was ca cu ated n Euros D sease sever ty was categor zed as m d (0 to 10 PAS score), moderate (10 1 to 20 PAS score) and severe (20 1 to 72 PAS score) at each year PAS Comb ned assessment of es on sever ty and area affected nto s ng e score Body was d v ded nto 4 sect ons head, arms, trunk, egs For each sect on, percent area of sk n nvo ved was est mated 0= 0% to 6= 90-100% Sever ty was est mated by c n ca s gns erythema, ndurat on, desquamat on; sca e 0= none to 4= max mum F na PAS = sum of sever ty parameters for each sect on*area score*we ght of sect on (head 0 1, arms 0 2, body 0 3, egs 0 4); tota poss b e score range 0= no d sease to 72= max ma d sease 'By year' ana ys s was not poss b e for those part c pants for whom the data of one or more v s ts was m ss ng	Year 1, 2, 3, 4, 5

Amount of Annua Cost for Part c pants Ar s ng From Out-of-Pocket Payment and Concom tant Med cat ons	Annua costs for part c pants for treatment w th etanercept due to out of pocket payments (nc uded payments wh ch were not re mbursed by the hea th nsurance funds) and concom tant med cat ons was reported per month for costs pr or to study and per year for each year n the study up to 5 years 'By year' ana ys s was not poss b e for those part c pants for whom the data of 1 or more v s ts was m ss ng	Pr or to study, Year 1, 2, 3, 4, 5
Effect of Drug-Free nterva on Pat ent's G oba Assessment of D sease Act v ty (PatGA)	Effect of drug-free nterva on PatGA was determ ned by compar ng the PatGA scores of the sub group Part c pants W thout Drug-Free nterva to that of the sub group Part c pants W th Drug-Free nterva PatGA part c pants were asked to rate the sever ty of the r d sease act v ty on a 6-po nt sca e, where 0 = no act v ty and 5 = severe or max mum act v ty	Week 0, 12, 24 of Cyc e 1 to 6
Effect of Drug-Free nterva on Dermato ogy L fe Qua ty ndex (DLQ) Score	Effect of drug free nterva on DLQ was determ ned by compar ng the scores of the sub group Part c pants W thout Drug-Free nterva to that of the sub group Part c pants W th Drug-Free nterva DLQ s the dermato ogy-spec fic qua ty of fe measure used for psor at c popu at on The 10- tem quest onna re has a score range of 0 to 30 w th h gher scores nd cat ng poor qua ty of fe An est mate of the m n ma c n ca y mportant d fference of the DLQ tota score s a 5 po nt mprovement Tota score range 0 (best) to 30 (worst)	Week 0, 12, 24 of Cyc e 1 to 6
Effect of Drug-Free nterva on Euro Qua ty of L fe-5 D mens ons (EQ-5D) T me Trade-Off (TTO)	Effect of drug free nterva on EQ-5D was determ ned by compar ng the scores of the sub group Part c pants W thout Drug-Free nterva to that of the sub group Part c pants W th Drug-Free nterva EQ-5D part c pant rated quest onna re to assess hea th-re ated qua ty of fe Hea th State Profi e component assesses eve of current hea th for 5 doma ns mob ty, se f-care, usua act v t es, pa n and d scomfort, and anx ety and depress on; 1 nd cates better hea th state (no prob ems); 3 nd cates worst hea th state (extreme prob ems) Score of each doma n s transformed nto a s ng e TTO va ue us ng formu a deve oped by Gre ner et a and resu ts n a tota score range -0 205 to 0 999; h gher score nd cates a better hea th state	Week 0, 12, 24 of Cyc e 1 to 6
Part c pant Percept on of Drug-Free nterva Length of Drug-Free nterva	A quest onna re was fi ed n by part c pants to eva uate the r percept on of drug-free nterva before the start of every drug-free nterva (after Cyc e 1, 2, 3, 4, 5) and after every drug-free nterva (before Cyc e 2, 3, 4, 5, 6) Before the drug-free nterva part c pants were asked, How ong do you expect the drug-free nterva to ast for? After the drug-free nterva part c pants were asked, How ong d d the drug-free nterva ast? Resu ts are reported for part c pant's percept on of the ength of drug-free nterva	Before Cyc e 2, 3, 4, 5, 6, after Cyc e 1, 2, 3, 4, 5
Part c pant Percept on of Drug-Free nterva Reason for Return ng to Pract ce	A quest onna re was fi ed n by part c pants to eva uate the r percept on of drug-free nterva before the start of every drug-free nterva (after Cyc e 1, 2, 3, 4, 5) and after every drug-free nterva (before Cyc e 2, 3, 4, 5, 6) After the drug-free nterva part c pants were asked, Why d d you return to the pract ce today? Responses nc uded unschedu ed v s t due to new occurrence of d sease, schedu ed v s t or other reasons (nc uded reasons ke treatment of adverse event, get a prescr pt on or exam nat on after externa treatment) Resu ts are reported for reasons for return ng to the pract ce	Before Cyc e 2, 3, 4, 5, 6

Part c pant Percept on of Drug-Free nterva L k ng of Drug-Free nterva	A quest onna re was fi ed n by part c pants to eva uate the r percept on of drug-free nterva before the start of every drug-free nterva (after Cyc e 1, 2, 3, 4, 5) and after every drug-free nterva (before Cyc e 2, 3, 4, 5, 6) Before the drug-free nterva part c pants were asked, Do you bas ca y ke the dea of a drug-free nterva ? After the drug-free nterva part c pants were asked, How d d you ke the current drug-free nterva ? Part c pants responded on a sca e of 1 (not at a) to 5 (very good) Resu ts are reported for part c pant's k ng of the drug-free nterva	Before Cyc e 2, 3, 4, 5, 6, after Cyc e 1, 2, 3, 4, 5
Part c pant Percept on of Drug-Free nterva Durat on	A quest onna re was fi ed n by part c pants to eva uate the r percept on of drug-free nterva before the start of every drug-free nterva (after Cyc e 1, 2, 3, 4, 5) and after every drug-free nterva (before Cyc e 2, 3, 4, 5, 6) After the drug-free nterva part c pants were asked, How wou d you assess the engh of the current drug-free nterva ? Part c pants responded on a sca e of 1 (too ong) to 5 (too short) Resu ts are reported for part c pant's percept on of the durat on of drug-free nterva	Before Cyc e 2, 3, 4, 5, 6
Part c pant Percept on of Drug-Free nterva Re apse of Symptoms	A quest onna re was fi ed n by part c pants to eva uate the r percept on of drug-free nterva before the start of every drug-free nterva (after Cyc e 1, 2, 3, 4, 5) and after every drug-free nterva (before Cyc e 2, 3, 4, 5, 6) Before the drug-free nterva part c pants were asked, How much are you concerned about a re apse of symptoms? After the drug-free nterva part c pants were asked, Were you concerned about a re apse of symptoms dur ng the drug-free nterva ? Part c pants responded on a sca e of 1 (not concerned) to 5 (very much concerned) Resu ts are reported for part c pant's percept on of re apse of symptoms	Before Cyc e 2, 3, 4, 5, 6, after Cyc e 1, 2, 3, 4, 5
Part c pant Percept on of Drug-Free nterva Effect ve Therapy After Drug-Free nterva	A quest onna re was fi ed n by part c pants to eva uate the r percept on of drug-free nterva before the start of every drug-free nterva (after Cyc e 1, 2, 3, 4, 5) and after every drug-free nterva (before Cyc e 2, 3, 4, 5, 6) Before the drug-free nterva part c pants were asked, To what extend are you re eved by the fact that there s an effect ve therapy after the drug-free nterva ? After the drug-free nterva part c pants were asked, To what extend were you re eved by the fact that there s an effect ve therapy after the drug-free nterva ? Part c pants responded on a sca e of 1 (not much re eved) to 5 (very much re eved) Resu ts are reported for part c pant's percept on of effect ve therapy after drug-free nterva	Before Cyc e 2, 3, 4, 5, 6, after Cyc e 1, 2, 3, 4, 5
Part c pant Percept on of Drug-Free nterva D sease Act v ty	A quest onna re was fi ed n by part c pants to eva uate the r percept on of drug-free nterva before the start of every drug-free nterva (after Cyc e 1, 2, 3, 4, 5) and after every drug-free nterva (before Cyc e 2, 3, 4, 5, 6) After the drug-free nterva part c pants were asked, How wou d you assess the act v ty of your d sease dur ng the first ha f of the drug-free nterva ? and How wou d you assess the act v ty of your d sease dur ng the second ha f of the drug-free nterva ? Part c pants responded on a sca e of 1 (no act v ty) to 5 (strongest poss b e act v ty) Resu ts are reported for part c pant's percept on of d sease act v ty dur ng the first ha f and second ha f of drug-free nterva	Before Cyc e 2, 3, 4, 5, 6

Part c pant Percept on of Drug-Free nterva Sat sfact on W th Sk n Cond t on	A quest onna re was fi ed n by part c pants to eva uate the r percept on of drug-free nterva before the start of every drug-free nterva (after Cyc e 1, 2, 3, 4, 5) and after every drug-free nterva (before Cyc e 2, 3, 4, 5, 6) After the drug-free nterva part c pants were asked, How much were you sat sfied w th the cond t on of your sk n dur ng the first ha f of the drug-free nterva ? and How much were you sat sfied w th the cond t on of your sk n dur ng the second ha f of the drug-free nterva ? Part c pants responded on a sca e of 1 (very d ssat sfied) to 5 (very sat sfied) Resu ts are reported for part c pant's sat sfact on w th the r sk n cond t on dur ng the first ha f and second ha f of drug-free nterva	Before Cyc e 2, 3, 4, 5, 6
Part c pant Percept on of Drug-Free nterva R sk for Adverse Drug React ons	A quest onna re was fi ed n by part c pants to eva uate the r percept on of drug-free nterva before the start of every drug-free nterva (after Cyc e 1, 2, 3, 4, 5) and after every drug-free nterva (before Cyc e 2, 3, 4, 5, 6) Before and after the drug-free nterva part c pants were asked to respond on a sca e of 1 (no agreement) to 5 (comp ete agreement) to the statement, A drug-free nterva reduces the r sk for adverse drug react ons Resu ts are reported for part c pant's percept on of r sk of adverse drug react ons	Before Cyc e 2, 3, 4, 5, 6, after Cyc e 1, 2, 3, 4, 5
Part c pant Percept on of Drug-Free nterva Rem nder of D sease	A quest onna re was fi ed n by part c pants to eva uate the r percept on of drug-free nterva before the start of every drug-free nterva (after Cyc e 1, 2, 3, 4, 5) and after every drug-free nterva (before Cyc e 2, 3, 4, 5, 6) Before and after the drug-free nterva part c pants were asked to respond on a sca e of 1 (no agreement) to 5 (comp ete agreement) to the statement, Dur ng drug-free nterva w not be rem nded permanent y of my d sease Resu ts are reported for part c pant's percept on of rem nder of d sease dur ng the drug-free nterva	Before Cyc e 2, 3, 4, 5, 6, after Cyc e 1, 2, 3, 4, 5
Part c pant Percept on of Drug-Free nterva Comfort n Everyday L fe	A quest onna re was fi ed n by part c pants to eva uate the r percept on of drug-free nterva before the start of every drug-free nterva (after Cyc e 1, 2, 3, 4, 5) and after every drug-free nterva (before Cyc e 2, 3, 4, 5, 6) Before and after the drug-free nterva part c pants were asked to respond on a sca e of 1 (no agreement) to 5 (comp ete agreement) to the statement, A drug-free nterva means more comfort n my everyday fe Resu ts are reported for part c pant's percept on of comfort of fe dur ng the drug-free nterva	Before Cyc e 2, 3, 4, 5, 6, after Cyc e 1, 2, 3, 4, 5
Part c pant Percept on of Drug-Free nterva Preference to Cont nuous Therapy	A quest onna re was fi ed n by part c pants to eva uate the r percept on of drug-free nterva before the start of every drug-free nterva (after Cyc e 1, 2, 3, 4, 5) and after every drug-free nterva (before Cyc e 2, 3, 4, 5, 6) Before and after the drug-free nterva part c pants were asked, f poss b e, wou d you prefer a cont nuous therapy w t out drug-free nterva ? Part c pants responded as yes or no to the quest on Resu ts are reported for part c pant's preference towards cont nuous therapy	Before Cyc e 2, 3, 4, 5, 6, after Cyc e 1, 2, 3, 4, 5
Part c pant Percept on of Drug-Free nterva Recommendat on of Therapy	A quest onna re was fi ed n by part c pants to eva uate the r percept on of drug-free nterva before the start of every drug-free nterva (after Cyc e 1, 2, 3, 4, 5) and after every drug-free nterva (before Cyc e 2, 3, 4, 5, 6) Before and after the drug-free nterva part c pants were asked, Wou d you recommend therapy w th Enbre to other pat ents w th	Before Cyc e 2, 3, 4, 5, 6, after Cyc e 1, 2, 3, 4, 5

	p aque-psor as s? Part c pants responded as yes or no to the quest on Resu ts are reported for part c pant's ke ness to recommend therapy	
Cr ter a for Treatment Resumpt on	Cr ter a for resumpt on of therapy for another cyc e by the phys c an were spec fied after the 5 drug-free nterva s as 1) new d sease act v ty (NDA), 2) prevent on of deter orat on (POD), 3) other reasons (nc uded reasons ke end of adverse event, frequent occurrence of adverse event or pre-spec fied therapy scheme), 4) new d sease act v ty and prevent on of deter orat on, 5) new d sease act v ty and other reason, 6) prevent on of deter orat on and other reason, and 7) new d sease act v ty, prevent on of deter orat on, and other reasons	Before Cyc e 2, 3, 4, 5, 6
Number of Part c pants W th Ser ous Adverse Events (SAEs) or Adverse Events (AEs)	An AE was any untoward med ca occurrence n a part c pant who rece ved study drug w thout regard to poss b ty of causa re at onsh p An SAE was an AE resu t ng n any of the fo ow ng outcomes or deemed s gn ficant for any other reason death; n t a or pro onged npat ent hosp ta zat on; fe-threaten ng exper ence (mmed ate r sk of dy ng); pers stent or s gn ficant d sab ty/ ncapac ty; congen ta anoma y Number of part c pants w th AEs nc uded part c pants affected w th both SAEs and non-SAEs	Cyc e 1 Week 0 up to 30 days after end of study (where end of study was Cyc e 6 Week 24)

Collaborators and Investigators

Th s s where you w find peop e and organ zat ons nvo ved w th th s study

Sponsor

Pfizer

Collaborators

No nformat on prov ded

Investigators

- Study D rector Pfizer CT gov Ca Center, Pfizer

Publications

The person respons b e for enter ng nformat on about the study vo untar y prov des these pub cat ons These may be about anyth ng re ated to the study

General Publications

No pub cat ons ava ab e

* Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.

Study Record Dates

These dates track the progress of study record and summary resu ts subm ss ons to C n ca Tr a s gov Study records and reported resu ts are rev ewed by the Nat ona L brary of Med c ne (NLM) to make sure they meet spec fic qua ty contro standards before be ng posted on the

pub c webs te

Study Registration Dates

First Submitted
2008-06-30

First Submitted that Met QC Criteria
2008-07-01

First Posted (Estimated)
2008-07-02

Results Reporting Dates

Results First Submitted
2014-12-19

Results First Submitted that Met QC Criteria
2015-07-24

Results First Posted (Estimated)
2015-07-27

Study Record Updates

Last Update Submitted that met QC Criteria
2015-07-24

Last Update Posted (Estimated)
2015-07-27

Last Verified
2015-07

More Information

Terms related to this study

Keywords Provided by Pfizer

P aque type psor as s

Additional Relevant MeSH Terms

Sk n D seases, Papu osquamous
Sk n D seases
Psor as s
Ant nflammatory Agents, Non Stero da
Ana ges cs, Non Narcot c
Ana ges cs
Sensory System Agents
Per phera Nervous System Agents
Phys o og ca Effects of Drugs
Ant nflammatory Agents
Ant rheumat c Agents
Gastro ntest na Agents
mmunosuppress ve Agents
mmuno og c Factors
Etanercept

Drug and device information, study documents, and helpful links

Study Documents

No study documents ava ab e

Helpful Links Provided by Pfizer

To obta n contact nformat on for a study center near you, c ck here (https //tr a nfoema pfizer com/pages/ and ng aspx?Study D=0881X1 4499&StudyName=Observat ona %20Study%20Eva uat ng%20etanercept%20%28Enbre %AE%29%20 n%20Subjects%20W th%20P aque Type%20Psor as s%20 n%20Usua %20Care%20Sett ngs)

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Record 1 of 1

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Read our full disclaimer (https://clinicaltrials.gov/about site/disclaimer) for details.

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

TERMINATED

The study was terminated after the European Medicines Agency recommended to suspend the marketing authorisation of Raptiva in the European Union

TRUST Study: Raptiva ® in Hand & Foot Psoriasis (TRUST)

ClinicalTrials.gov ID **NCT00739882**

Sponsor Merck KGaA, Darmstadt, Germany

Information provided by Merck KGaA, Darmstadt, Germany (Responsible Party)

Last Update Posted 2014 02 27

Study Details Tab

Study Overview

Brief Summary

Feedback

To evaluate the safety and efficacy of Raptiva ® compared with placebo to control chronic moderate to severe plaque psoriasis involving the hands and/or feet scoring Physician s Global Assessment (PGA H&F) greater than or equal to 3 in subjects not suitable for other systemic therapies including cyclosporine, methotrexate, and Psoralen Ultraviolet Light A (PUVA).

Official Title

A Phase IV Multicentre, Randomised, Double blind, Placebo Controlled, Trial to Evaluate the Safety and Efficacy of Raptiva ® in the Treatment of Subjects With Moderate to Severe Plaque Psoriasis Involving Hands and/or Feet, With or Without Pustules.

Conditions

Chronic Plaque Psoriasis

Intervention / Treatment

- Drug: Efalizumab anti CD11a recombinant human monoclonal antibody
- Drug: Placebo

Other Study ID Numbers

- 27808

Study Start

2008 04

Primary Completion (Actual)

2009 06

Study Completion (Actual)

2009 06

Enrollment (Actual)

76

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Foot Health (https://medlineplus.gov/foothealth.html) Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Austria

Vienna, Austria
University of Vienna Medical School

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person s general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

1. Subject with chronic (disease history of at least 6 months from diagnosis) moderate to severe plaque psoriasis involving the hands and/or feet (PGA H&F ratings of 3 or 4) at screening, who have failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including cyclosporin, methotrexate and PUVA. Subjects will be outpatients.
2. Stable disease at study entry (i.e. no exacerbation of psoriasis during the screening period).
3. At least 18 years old.
4. For women of childbearing potential, use of an acceptable method of contraception to prevent pregnancy and agreement to continue to practice an acceptable method of contraception for the duration of their participation in the study. For men, during the participation, it is mandatory to practice birth control, as there are not existing data on the effect of Raptiva ® on spermatogenesis.
5. Discontinuation of any systemic psoriasis treatment at study entry. No washout period is required for these traditional systemic psoriasis agents prior to starting study treatment.
6. Discontinuation of all biological agents at least 3 months prior to first study injection.
7. Discontinuation of any investigational drug or treatment at least 3 months prior to SD 1 or as per washout requirements from previous protocol.
8. Willingness and ability to comply with the protocol requirements for the duration of the study.
9. Written informed consent, given prior to any study related procedure not part of normal medical care, with the understanding that the subject may withdraw his/her consent at any time without prejudice to future medical care.

Exclusion Criteria:

1. Hypersensitivity to efalizumab or to any of the excipients
2. Current use of any prohibited therapy (systemic or topical treatments for psoriasis, immunosuppressive drugs, any other experimental drug, etc)
3. Previous or current exposure to Raptiva®
4. History of or ongoing alcohol or drug abuse
5. History of or an ongoing opportunistic infection (e.g. systemic fungal infection, parasites) or any other serious infection. This includes diagnoses that required more than 2 weeks of therapy, such as endocarditis and osteomyelitis, that have been treated in the past 6 months. In addition, if the subject is currently receiving antibiotics, antivirals, or antifungals for an infection or for suppression or prophylaxis for any diagnosis, the subject will be excluded.
6. Seropositivity for hepatitis B antigen, hepatitis C antibody, or human immunodeficiency virus (HIV). Subjects will undergo testing during screening, and any subjects who are seropositive for hepatitis B antigen, hepatitis C antibody, or HIV will be excluded.

7. History of active or latent tuberculosis within one year prior to screening (to be determined by assessment according to national and/or local recommendation).
8. Presence or history of malignancy, including lymphoproliferative disorders.
9. Pregnancy or breast feeding
10. History of hepatic cirrhosis, regardless of cause or severity
11. History of thrombocytopenia, haemolytic anaemia, clinically significant anaemia, a white blood cell count <4,000 cells/µL or >14,000 cells/µL, a haematocrit (HCT) <30% or a haemoglobin (Hgb) level <11 g/dL, a platelet count <150,000 cells/µL
12. Hepatic enzyme levels ≥3 times the upper limit of normal or serum creatinine level ≥2 times the upper limit of normal
13. Vaccination with a live or live attenuated virus or live or live attenuated bacteria vaccine within the 14 days prior to the first dose of Raptiva®
14. Any medical condition that, in the judgment of the Investigator, would jeopardise the subject s safety following exposure to investigational medicinal product (Raptiva® or placebo equivalent) or would significantly interfere with the Subject s ability to comply with the provisions of this protocol.
15. Other specific forms of psoriasis like guttate, erythrodermic or pustular psoriasis as sole or predominant for of psoriasis.
16. Immunodeficiencies.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Active Comparator: Efalizumab	Drug: Efalizumab - anti CD11a recombinant human monoclonal antibody • Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week. The treatment period will be 24 weeks divided into two phases: 1) double-blind for 12 weeks, and 2) open-label for 12 additional weeks, in which all subjects from the placebo group and those subjects from the Raptiva ® group with ≥ 50% of improvement will be allocated to extended treatment with Raptiva ® for 12 additional weeks while non-responders to Raptiva ® (improvement ≤ 50%) will be followed in an observational manner for 12 additional weeks without treatment.
Placebo Comparator: Placebo	Drug: Placebo • Placebo will be administered at Study Day (SD) 1, Week (W) 1, W 4, W 8 and W 12. Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week for 12 weeks (double-blind phase)

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Proportion Of Participants Achieving A Physicians Global Assessment - Hand & Foot (PGA - H&F) Rating Of Clear, Almost Clear Or Mild At Week 12	The proportion of subjects achieving a PGA - H&F rating of clear, almost clear, or mild at Week 12: Clear - No signs of plaque psoriasis on the hands and/or feet; Almost Clear - Just perceptible erythema and just perceptible scaling on the hands and/or feet; Mild - Light pink erythema with minimal scaling and with or without pustules on the hands and/or feet	12 weeks

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Proportion Of Participants Achieving A Physicians Global Assessment - Hand & Foot (PGA - H&F) Rating Of Clear, Or Almost Clear At Week 12	The proportion of participants achieving a PGA - H&F rating of clear, or almost clear, at Week 12: Clear - No signs of plaque psoriasis on the hands and/or feet; Almost Clear - Just perceptible erythema and just perceptible scaling on the hands and/or feet	12 weeks
Proportion Of Participants Achieving A Physicians Global Assessment -	The proportion of participants achieving a PGA - H&F rating of clear, almost clear, or mild at Week 24: Clear - No signs of plaque psoriasis on the hands and/or feet; Almost Clear - Just perceptible	24 weeks

Hand & Foot (PGA - H&F) Rating Of Clear, Almost Clear Or Mild At Week 24	erythema and just perceptible scaling on the hands and/or feet; Mild - Light pink erythema with minimal scaling and with or without pustules on the hands and/or feet	
Proportion of Participants From the Initial Placebo Group Achieving a PGA - H&F of Rating of Clear, Almost Clear, or Mild From Week 12 to Week 24.	The proportion of participants achieving a PGA - H&F rating of clear, or almost clear, at Week 24: Clear - No signs of plaque psoriasis on the hands and/or feet; Almost Clear - Just perceptible erythema and just perceptible scaling on the hands and/or feet; Mild - Light pink erythema with minimal scaling and with or without pustules on the hands and/or feet	24 weeks
Proportion Of Participants Achieving A Physicians Global Assessment (PGA) Rating of Good, Excellent, Or Cleared At Week 12	The proportion of participants achieving a PGA rating of good, excellent, or cleared at Week 12. Cleared = 100% improvement; Excellent = 75-99% improvement; Good = 50-74% improvement	12 weeks
Proportion Of Participants Achieving A Physicians Global Assessment (PGA) Rating of Excellent, Or Cleared At Week 12	The proportion of participants achieving a PGA rating of excellent, or cleared at Week 12. Cleared = 100% improvement; Excellent = 75-99% improvement	12 weeks

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Merck KGaA, Darmstadt, Germany

Collaborators

No information provided

Investigators

- Study Director: Nicole Selenko Gebauer, MD, Merck Serono S.A., Geneva

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

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Study Registration Dates

First Submitted

2008-08-20

First Submitted that Met QC Criteria

2008-08-21

First Posted (Estimated)

2008-08-22

Results Reporting Dates

Results First Submitted

2010-06-28

Results First Submitted that Met QC Criteria

2010-08-04

Results First Posted (Estimated)

2010-08-30

Study Record Updates

Last Update Submitted that met QC Criteria

2014-01-26

Last Update Posted (Estimated)

2014-02-27

Last Verified

2014-01

More Information

Terms related to this study

Keywords Provided by Merck KGaA, Darmstadt, Germany

Efalizumab,
Chronic plaque psoriasis
moderate to severe
involving
hands

feet

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Immunologic Factors
Physiological Effects of Drugs
Antibodies
Antibodies, Monoclonal

Study Documents

No study documents available

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Record 1 of 1

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

A Safety and Effectiveness Study of CNTO 1275 in Patients With Moderate to Severe Plaque-type Psoriasis

ClinicalTrials.gov ID **NCT00320216**

Sponsor Centocor, Inc.

Information provided by Centocor, Inc. (Responsible Party)

Last Update Posted 2015 04 20

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to evaluate the efficacy and safety of initial single and multiple subcutaneous injections of CNTO 1275 in the treatment of patients with moderate to severe plaque psoriasis.

Feedback

Detailed Description

This is a randomized (the study medication is assigned by chance), double blind (neither physician nor patient knows the treatment that the patient receives), parallel group, multicenter study to determine the effectiveness and safety of two different doses of CNTO 1275 administered subcutaneously one time or as multiple doses as compared with placebo in patients with moderate to severe plaque type psoriasis (the most common type of psoriasis). The dose of CNTO 1275 will be 45 or 90 mg administered subcutaneously once or as four weekly doses. Patients who inadequately respond to their treatment may receive one additional dose. Patients will be monitored for the safety throughout the study.

Official Title

A Phase II, Randomized, Double blind, Placebo controlled, Parallel Study of Single and Multiple Dose Regimens With Subcutaneous CNTO 1275 (Human Monoclonal Antibody to IL 12) in Subjects With Moderate to Severe Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Ustekinumab
- Drug: Placebo

Other Study ID Numbers

- CR005416
- C0379T04 (Other Identifier) (OTHER: Centocor)

Study Start

2003 11

Primary Completion (Actual)

2004 06

Study Completion (Actual)

2005 03

Enrollment (Actual)

320

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Ustekinumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Ustekinumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

No location data

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person s general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Have had a diagnosis of plaque type psoriasis at least 6 months
- Plaque type psoriasis covering at least 10% of total body surface areas
- Psoriasis area and severity index score of 12 or greater
- Considered by treating dermatologist to be a candidate for phototherapy or systemic treatment of psoriasis
- Women of childbearing potential and all men must agree to use adequate birth control measures
- Have no history of latent or active tuberculosis

Exclusion Criteria:

- Currently have nonplaque forms of psoriasis or drug induced psoriasis
- Women who are pregnant or nursing, or men and women planning pregnancy while enrolled in the study
- Patients who have a history of chronic or recurrent infectious disease or who have or have had a serious infection requiring hospitalization or intravenous antibiotics within the previous 2 months
- Patients who have or ever have had a nontuberculous mycobacterial infection or opportunistic infection
- Patients known to be infected with human immunodeficiency virus, hepatitis B, or hepatitis C
- Patients who have current signs or symptoms of severe, progressive, or uncontrolled renal, hepatic, hematological, gastrointestinal, endocrine, pulmonary, cardiac, neurologic, cerebral, or psychiatric disease
- Have any known malignancy or have a history of malignancy within the previous 5 years (with the exception of basal cell carcinoma of the skin that has been treated with no evidence of recurrence)

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Placebo Comparator: Group I (Placebo) Patients in the placebo group will receive placebo at Weeks 0, 1, 2, 3, and 16. At week 20, all patients will receive a single dose of ustekinumab 90 mg.	Drug: Placebo • Patients in the placebo group will receive placebo medication.
Experimental: Group II (Ustekinumab 45 mg) Patients will receive single dose ustekinumab at Week 0 and placebo at Weeks 1, 2, and 3. At Week 16, patients with Physicians Global Assessment (PGA) greater than or equal to 3 will receive ustekinumab 45 mg. At week 20, all patients will receive placebo.	Drug: Ustekinumab • Patients will receive subcutaneous injections of ustekinumab (45 or 90 mg). • Other Names: ◦ CNTO 1275 Drug: Placebo • Patients in the placebo group will receive placebo medication.
Experimental: Group III (Ustekinumab 90 mg) Patients will receive 90 mg single dose ustekinumab at Week 0 and placebo at Weeks 1, 2, and 3. At	Drug: Ustekinumab • Patients will receive subcutaneous injections of ustekinumab (45 or 90 mg). • Other Names: ◦ CNTO 1275 Drug: Placebo

Week 16 patients with PGA greater than or equal to 3 will receive ustekinumab 90 mg. At week 20, all patients will receive placebo.	• Patients in the placebo group will receive placebo medication.
Experimental: Group IV Patients will receive 45 mg of ustekinumab at Weeks 0, 1, 2, and 3. At Week 16, patients with Physicians Global Assessment (PGA) greater than or equal to 3 will receive ustekinumab 45 mg. At week 20, all patients will receive placebo.	Drug: Ustekinumab • Patients will receive subcutaneous injections of ustekinumab (45 or 90 mg). • Other Names: ◦ CNTO 1275
Experimental: Group V Patients will receive 90 mg of ustekinumab at Weeks 0, 1, 2, and 3. At Week 16 patients with Physicians Global Assessment (PGA) greater than or equal to 3 will receive ustekinumab 90 mg. At week 20, all patients will receive placebo.	Drug: Ustekinumab • Patients will receive subcutaneous injections of ustekinumab (45 or 90 mg). • Other Names: ◦ CNTO 1275

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants Who Achieved Psoriasis Area and Severity Index (PASI) 75% Improvement at Week 12	Psoriasis Area and Severity Index (PASI)(0 [best] -72 [worst]) score at Week 12. This is a test of how bad a persons psoriasis is. The combination of redness, scaling, and thickness, as well as overall body involvement determine the PASI score.	Week 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants Who Achieved Physicians Global Assessment (PGA) Score of Clear (1) or Excellent (2) at Week 12	Number of participants achieving a physician global assessment (PGA)(1 [best] to 6 [worst]) score of clear or excellent at Week 12. The PGA is used to determine the participants psoriasis lesions overall at a given time point. Overall lesions will be graded for induration, erythema, and scaling. The sum of the 3 scales will be divided by 3 to obtain a final PGA score.	Week 12
Number of Participants Who Achieved Psoriasis Area Severity Index (PASI) 75% Improvement at Week 32	Psoriasis Area and Severity Index (PASI)(0 [best] -72 [worst]) score at Week 32 for participants who were not retreated at Week 16. This is a test of how bad a persons psoriasis is. The combination of redness, scaling, and thickness, as well as overall body involvement determine the PASI score.	Week 32

Number of Participants Who Achieved Psoriasis Area Severity Index (PASI) 75% Improvement (0-72) at Week 28	Psoriasis Area and Severity Index (PASI)(0 [best] -72 [worst]) score at Week 28 for participants who were retreated at Week 16. This is a test of how bad a persons psoriasis is. The combination of redness, scaling, and thickness, as well as overall body involvement determine the PASI score.	Week 28

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Centocor, Inc.

Collaborators

No information provided

Investigators

- Study Director: Centocor, Inc. Clinical Trial, Centocor, Inc.

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

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Study Record Dates

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Study Registration Dates

First Submitted
2006-04-28

First Submitted that Met QC Criteria
2006-04-28

First Posted (Estimated)
2006-05-03

Results Reporting Dates

Results First Submitted
2009-10-23

Results First Submitted that Met QC Criteria
2012-11-20

Results First Posted (Estimated)
2012-12-19

Study Record Updates

Last Update Submitted that met QC Criteria
2015-03-31

Last Update Posted (Estimated)
2015-04-20

Last Verified
2015-03

More Information

Terms related to this study

Keywords Provided by Centocor, Inc.

Psoriasis
CNTO 1275
Ustekinumab
Stelara
Interleukin 12
IL 12
Interleukin 23
IL 23

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Dermatologic Agents
Ustekinumab

Study Documents

No study documents available

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Before jo n ng a study, ta k to your hea th care profess ona about poss b e r sks and benefits To earn more about tak ng part n stud es, read Learn About Stud es (https //c n ca tr a s gov/study bas cs/ earn about stud es)

COMPLETED

Study Evaluating Etanercept for the Treatment of Moderate to Severe Psoriasis (PRISTINE)

ClinicalTrials.gov ID NCT00663052

Sponsor Pfizer

Information provided by Pfizer (Respons b e Party)

Last Update Posted 2012 04 23

Study Details Tab

Study Overview

Brief Summary

The purpose of th s study s to compare the safety and efficacy of d fferent doses of etanercept for the treatment of moderate to severe psor as s

Official Title

A Random zed, Doub e B nd Tr a Assess ng the Efficacy and Safety of Etanercept 50 mg Tw ce Week y and Etanercept 50 mg Once Week y for the Treatment of Moderate to Severe Psor as s

Conditions

P aque Psor as s Psor as s

Intervention / Treatment

- Drug Etanercept
- Drug Etanercept

Other Study ID Numbers

- 0881A6 4425
- B1801013

Feedback

Study Start

2008 06

Primary Completion (Actual)

2010 01

Study Completion (Actual)

2010 01

Enrollment (Actual)

273

Study Type

ntervent ona

Phase

Phase 4

Resource links provided by the National Library of Medicine

Med neP us (https //med nep us gov/) re ated top cs Psor as s (https //med nep us gov/psor as s htm)

Drug nformat on (https //da ymed n m n h gov/da ymed/) ava ab e for Etanercept (https //da ymed n m n h gov/da ymed/search cfm? abe type=human&query=Etanercept)

Other U S FDA Resources (https //c ass c c n ca tr a s gov/ct2/ nfo/fda nks)

Contacts and Locations

Th s sect on prov des the contact deta s for those conduct ng the study, and nformat on on where th s study s be ng conducted

Argentina

Buenos Aires Locations

Capital Federal, Buenos Aires, Argentina, 01114
Pfizer nves iga ional Si e

Capital Federal, Buenos Aires, Argentina, 01199
Pfizer nves iga ional Si e

San Miguel, Buenos Aires, Argentina, 1684
Pfizer nves iga ional Si e

Austria

C ck to v ew nteract ve map

Participation Criteria

Researchers ook for peop e who fit a certa n descr pt on, ca ed e g b ty cr ter a Some examp es of these cr ter a are a person's genera hea th cond t on or pr or treatments

For genera nformat on about c n ca research, read Learn About Stud es (https //c n ca tr a s gov/study bas cs/ earn about stud es)

Eligibility Criteria

Description

nc us on Cr ter a

- 18 years of age or o der at t me of consent
- Act ve, moderate to severe chron c p aque psor as s defined by the fo ow ng cr ter a C n ca y stab e, p aque psor as s nvo v ng greater than or equa to 10% body surface area (BSA) or PAS greater than or equa to 10
- n the op n on of the nvest gator, fa ure, nto erance, contra nd cat on or not a cand date for the fo ow ng Methotrexate (MTX), cyc ospor ne and psora en p us u trav o et A rad at on (PUVA) therapy

Exc us on Cr ter a

- Ev dence of sk n cond t ons (e g , eczema) other than psor as s that wou d nterfere w th eva uat ons of the effect of study med cat on on psor as s
- Rheumato og c d sease such as rheumato d arthr t s, system c upus erythematous, system c vascu t s, sc eroderma and po ymyos t s, or assoc ated syndromes
- Act ve or recent (w th n 2 years) tubercu os s (TB) nfect on

Ages Eligible for Study

18 Years and o der (Adu t, O der Adu t)

Sexes Eligible for Study

A

Accepts Healthy Volunteers

No

Study Plan

Th s sect on prov des deta s of the study p an, nc ud ng how the study s des gned and what the study s measur ng

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Random zed
Interventional Model : S ng e Group Ass gnment
Masking : Doub e (Part c pant, nvest gator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Exper menta Group A A	Drug Etanercept • ETN 50 mg QW + PBO QW for 12 weeks fo owed by ETN 50 mg QW for 12 weeks
Exper menta Group B B	Drug Etanercept • ETN 50 mg B W for 12 weeks fo owed ETN 50 mg QW for 12 weeks

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Part c pants Ach ev ng a 75% mprovement From Base ne n Psor as s Area and Sever ty ndex (PAS) Score at Week 24	PAS Comb ned assessment of es on sever ty and area affected nto s ng e score; range 0(no d sease) to 72(max ma d sease) Body was d v ded nto 4 sect ons (head, arms, trunk, egs); each area was scored by tse f and scores were comb ned for fina PAS For each sect on percent area of sk n nvo ved was est mated 0 (0%) to 6 (90 - 100%), and sever ty was est mated by c n ca s gns erythema, ndurat on, and desquamat on; sca e 0 (none) to 4 (max mum) F na PAS = sum of sever ty parameters for each sect on * area score * we ght of sect on (head 0 1, arms 0 2, body 0 3, egs 0 4)	Week 24

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Part c pants Ach ev ng a 50% mprovement From Base ne n Psor as s Area and Sever ty ndex (PAS) Score at Each V s t Through Week 24	PAS Comb ned assessment of es on sever ty and area affected nto s ng e score; range 0(no d sease) to 72(max ma d sease) Body was d v ded nto 4 sect ons (head, arms, trunk, egs); each area was scored by tse f and scores were comb ned for fina PAS For each sect on percent area of sk n nvo ved was est mated 0 (0%) to 6 (90 - 100%), and sever ty was est mated by c n ca s gns erythema, ndurat on, and desquamat on; sca e 0 (none) to 4 (max mum) F na PAS = sum of sever ty parameters for each sect on * area score * we ght of sect on (head 0 1, arms 0 2, body 0 3, egs 0 4)	Base ne to Week 24
Percentage of Part c pants Ach ev ng a 75% mprovement From Base ne n Psor as s Area and Sever ty ndex (PAS) Score at Each V s t Through Week 24	PAS Comb ned assessment of es on sever ty and area affected nto s ng e score; range 0(no d sease) to 72(max ma d sease) Body was d v ded nto 4 sect ons (head, arms, trunk, egs); each area was scored by tse f and scores were comb ned for fina PAS For each sect on percent area of sk n nvo ved was est mated 0 (0%) to 6 (90 - 100%), and sever ty was est mated by c n ca s gns erythema, ndurat on, and desquamat on; sca e 0 (none) to 4 (max mum) F na PAS = sum of sever ty parameters for each sect on * area score * we ght of sect on (head 0 1, arms 0 2, body 0 3, egs 0 4)	Base ne to Week 24
Percentage of Part c pants Ach ev ng a 90% mprovement From Base ne n Psor as s Area and Sever ty ndex (PAS) Score at Each V s t Through Week 24	PAS Comb ned assessment of es on sever ty and area affected nto s ng e score; range 0(no d sease) to 72(max ma d sease) Body was d v ded nto 4 sect ons (head, arms, trunk, egs); each area was scored by tse f and scores were comb ned for fina PAS For each sect on percent area of sk n nvo ved was est mated 0 (0%) to 6 (90 - 100%), and sever ty was est mated by c n ca s gns erythema, ndurat on, and desquamat on; sca e 0 (none) to 4 (max mum) F na PAS = sum of sever ty parameters for each sect on * area score * we ght of sect on (head 0 1, arms 0 2, body 0 3, egs 0 4)	Base ne to week 24
Percentage of Part c pants Ach ev ng a 100% mprovement From	PAS Comb ned assessment of es on sever ty and area affected nto s ng e score; range 0(no d sease) to 72(max ma d sease) Body was d v ded nto 4 sect ons (head, arms, trunk, egs); each area was scored	Base ne to Week 24

Base ne n Psor as s Area and Sever ty ndex (PAS) Score at Each V s t Through Week 24	by tse f and scores were comb ned for fina PAS For each sect on percent area of sk n nvo ved was est mated 0 (0%) to 6 (90 - 100%), and sever ty was est mated by c n ca s gns erythema, ndurat on, and desquamat on; sca e 0 (none) to 4 (max mum) F na PAS = sum of sever ty parameters for each sect on * area score * we ght of sect on (head 0 1, arms 0 2, body 0 3, egs 0 4)	
Change From Base ne n Psor as s Area and Sever ty ndex (PAS) Score at Each V s t Through Week 24	PAS Comb ned assessment of es on sever ty and area affected nto s ng e score; range 0(no d sease) to 72(max ma d sease) Body was d v ded nto 4 sect ons (head, arms, trunk, egs); each area scored by tse f and scores were comb ned for fina PAS For each sect on, percent area of sk n nvo ved est mated 0 (0%) to 6 (90 - 100%), and sever ty was est mated by c n ca s gns erythema, ndurat on, and desquamat on; sca e 0 (none) to 4 (max mum) F na PAS = sum of sever ty parameters for each sect on * area score * we ght of sect on (head 0 1, arms 0 2, body 0 3, egs 0 4)	Base ne to Week 24
T me to Ach eve Psor as s Area and Sever ty ndex (PAS) 50, PAS 75 and PAS 100 Over 24 Weeks	T me taken to ach eve first PAS was ca cu ated us ng Kap an-Me er est mate and presented as med an PAS 50=50% mprovement from base ne n PAS ; PAS 75=75% mprovement from base ne n PAS ; PAS 90=90% mprovement from base ne n PAS ; PAS 100=100% mprovement from base ne n PAS PAS score percent mprovement =100*(base ne score - v s t score)/base ne score	Base ne to Week 24
Percentage of Part c pants Ach ev ng the Phys c an G oba Assessment (PGA) of Psor as s Responses of C ear (0) at Each V s t Through Week 24	PGA of Psor as s score based on dermato og st's assessment of head, sca p, and neck psor as s (averaged over a es ons) The PGA of Psor as s sca e ranges from 0 (no psor as s) to 5 (severe d sease) PGA score of 0 = Status of C ear	Base ne to Week 24
Percentage of Part c pants Ach ev ng the Phys c an G oba Assessment (PGA) of Psor as s Responses C ear/A most C ear (0, 1) at Each V s t Through Week 24	PGA of Psor as s score based on dermato og st's assessment of head, sca p, and neck psor as s (averaged over a es ons) The PGA of Psor as s sca e ranges from 0 (no psor as s) to 5 (severe d sease) PGA score of 0 = Status of C ear; 1 = A most C ear	Base ne to Week 24
Percentage of Part c pants Ach ev ng the Phys c an G oba Assessment (PGA) of Psor as s Responses of C ear/A most C ear/M d (0, 1, 2) at Each V s t Through Week 24	PGA of Psor as s score based on dermato og st's assessment of head, sca p, and neck psor as s (averaged over a es ons) The PGA of Psor as s sca e ranges from 0 (no psor as s) to 5 (severe d sease) PGA score of 0 = Status of C ear; 1 = A most C ear and 2 = M d	Base ne to Week 24
T me to F rst Phys c an G oba Assessment (PGA) of Psor as s of	T me taken to ach eve PGA was ca cu ated us ng Kap an-Me er est mate and presented as med an Assessment of c ear or a most c ear or M d	Base ne to Week 24

C ear/A most C ear (0, 1), or C ear/A most C ear/M d (0, 1, 2) Over 24 Weeks	= PGA score of 0 (no ev dence) or 1 (m n ma /fa nt) or 2 (m d p aque e evat on, m d fine sca es predom nates or ght red co orat on)	
Change From Base ne n Phys c an G oba Assessment (PGA) of Psor as s at Each V s t Through Week 24	PGA of Psor as s score based on dermato og st's assessment of d sease averaged over a es ons of head, sca p, and neck Overa es ons were graded for ndurat on, erythema, and sca ng; range 0 (no ev dence) to 5 (severe) The sum of the 3 scores was d v ded by 3 to obta n a fina PGA score H gher scores nd cate greater sever ty of d sease	Base ne to Week 24
Change From Base ne n Percent Body Surface Area (BSA) nvo vement of Psor as s at Each V s t Through Week 24		Base ne to Week 24
Change From Base ne n the Photographed mage of Les ons n Se ected Part c pants	Compare the before and after photographs w th the c n ca assessments (Psor as s Area and Sever ty ndex, Phys c an's G oba Assessment) taken at the same t me for ustrat on purposes Measured as yes or no for change	Base ne to Week 24
Percentage of Part c pants Not Us ng Top ca Preparat ons at Each V s t From Week 12 Through Week 24	Moderate top ca stero ds to very potent top ca stero ds, top ca v tam n D ana ogs, top ca stero ds n comb nat on w th v tam n D ana ogs, and anthra n compounds were proh b ted for 14 days before the base ne v s t unt week 12	From Week 12 to Week 24
Mean Psor as s Subject Sat sfact on Quest onna re (PSSQ) Scores at Week 12	PSSQ part c pant's assessment that nc udes 18 tems, 16 tems (1-16) scored us ng L kert score w th scores from 0 (very d ssat sfied) to 4 (very sat sfied) and 5 (never had th s prob em) On y those part c pants who do not have score of 5 at base ne nc uded n the tem 1-16 ana yses Two tems (17, 18) are w th Yes/No answers The scores of tems 1-16 for change from base ne are summar zed here	Week 12
Mean Psor as s Subject Sat sfact on Quest onna re (PSSQ) Scores at Week 24	PSSQ part c pant's assessment that nc udes 18 tems, 16 tems (1-16) scored us ng L kert score w th scores from 0 (very d ssat sfied) to 4 (very sat sfied) and 5 (never had th s prob em) On y those part c pants who do not have score of 5 at base ne nc uded n the tem 1-16 ana yses Two tems (17, 18) are w th Yes/No answers The scores of tems 1-16 for change from base ne are summar zed here	Week 24

Other Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Base ne n Subject G oba Assessment (SGA) of tch ng at Each V s t Through Week 24	SGA of Psor as s score based on part c pant's assessment of tch ng at a sca e of 0 to 5; where 0 = no tch ng and 5 = severe tch ng	Base ne to Week 24

Change From Base ne n Subject G oba Assessment (SGA) of Jo nt Pa n at Each V s t Through Week 24	SGA of Jo nt Pa n score based on part c pant's assessment of jo nt pa n at a sca e of 0 to 5; where 0 = no pa n and 5 = severe pa n	Base ne to Week 24
Change From Base ne n Subject G oba Assessment (SGA) of Psor as s at Each V s t Through Week 24	SGA of Psor as s score based on part c pant's assessment of psor as s d sease act v ty at a sca e of 0 to 5; where 0 = good and 5 = severe	Base ne to Week 24
Change From Base ne n Psor at c Arthr t s Screen ng and Eva uat on (PASE) Tota Score at Week 12	PASE a part c pant-adm n stered quest onna re and a s mp e scor ng system to ass st phys c ans n screen ng part c pants w th psor as s for ev dence of psor at c arthr t s w th two sub-sca es system sub-sca e and funct on sub-sca e Tota of 15 quest ons n both sub-sca es (7 quest ons n system and 8 n funct on sub-sca e) to score from 1 to 5; where 1 = strong y d sagree and 5 = strong y agree The tota of system and funct on scores prov des the tota PASE score rang ng from 15 to 75 where h gher scores nd cate greater sever ty	Base ne, Week 12
Percentage of Part c pants Eva uated Us ng Psor as s Phys c an Sat sfact on Quest onna re (PPSQ) Cons der Pat ent's Cond t on Sat sfactory From Base ne at Each V s t Through Week 24	Phys c an Psor as s Sat sfact on Quest onna re (PPSQ) nc uded two g oba sat sfact on quest ons to wh ch phys c ans respond e ther 'sat sfactory' or 'not sat sfactory ' These are 1) whether the part c pant's current cond t on s sat sfactory, cons der ng psor as s symptoms, sk n appearance and a other prob ems that psor as s causes; 2) whether the part c pant's current pr mary psor as s therapy s sat sfactory, cons der ng psor as s symptoms, sk n appearance, therapy s de effects and therapy ease/d fficu ty of use Each of these quest ons was summar zed for change from base ne	Base ne to Week 24
Percentage of Part c pants Eva uated by Phys c ans Us ng Psor as s Phys c an Sat sfact on Quest onna re (PPSQ) Cons der Pr mary Psor as s Therapy Sat sfactory From Base ne at Each V s t Through Week 24	Phys c an Psor as s Sat sfact on Quest onna re (PPSQ) nc udes two g oba sat sfact on quest ons to wh ch phys c ans respond e ther 'sat sfactory' or 'not sat sfactory ' These are 1) whether the part c pant's current cond t on s sat sfactory, cons der ng psor as s symptoms, sk n appearance and a other prob ems that psor as s causes; 2) whether the part c pant's current pr mary psor as s therapy s sat sfactory, cons der ng psor as s symptoms, sk n appearance, therapy s de effects and therapy ease/d fficu ty of use Each of these quest ons was summar zed for change from base ne	Base ne to Week 24
Percentage of Part c pants Who Were Cons dered Sat sfied W th Hea th State Accord ng to Psor as s Subject Sat sfact on Quest onna re (PSSQ)	PSSQ part c pant's assessment that nc udes 18 tems, 16 tems (1-16) scored us ng L kert score w th scores from 0 (very d ssat sfied) to 4 (very sat sfied) and 5 (never had th s prob em) On y those part c pants who do not have score of 5 at base ne nc uded n the tem 1-16 ana yses Two tems (17, 18) w th Yes/No answers are summar zed here	Base ne to Week 24

Percentage of Part c pants Who Were Cons dered Sat sfied W th Pr mary Psor as s Treatment Accord ng to Psor as s Subject Sat sfact on Quest onna re (PSSQ)	PSSQ part c pant's assessment that nc udes 18 tems, 16 tems (1-16) scored us ng L kert score w th scores from 0 (very d ssat sfied) to 4 (very sat sfied) and 5 (never had th s prob em) On y those part c pants who do not have score of 5 at base ne nc uded n the tem 1-16 ana yses Two tems (17, 18) w th Yes/No answers are summar zed here	Base ne to Week 24
Change From Base ne n Dermato ogy L fe Qua ty ndex (DLQ) Tota Score to Week 24	DLQ s the dermato ogy-spec fic qua ty of fe measure used for psor at c popu at on The 10- tem quest onna re has a score range of 0 to 30 w th h gher scores nd cat ng poor qua ty of fe An est mate of the m n ma c n ca y mportant d fference of the DLQ tota score s a 5 po nt mprovement Tota score range 0 (best) to 30 (worst)	Base ne to Week 24
Change From Base ne n the Euro Qua ty of L fe 5 D mens on (EQ-5D) Ut ty ndex	EQ-5D part c pant rated quest onna re to assess hea th-re ated qua ty of fe n terms of s ng e ut ty score Hea th State Profi e component assesses eve of current hea th for 5 doma ns mob ty, se f-care, usua act v t es, pa n and d scomfort, and anx ety and depress on; 1 nd cates better hea th state (no prob ems); 3 nd cates worst hea th state (examp e confined to bed) Scor ng formu a deve oped by EuroQo Group ass gns ut ty va ue for each doma n n the profi e Score s transformed and resu ts n tota score range -0 594 to 1 000; h gher score nd cates better hea th state	Base ne, Week 12 and Week 24
Change From Base ne n the Hosp ta Anx ety and Depress on Sca e (HADS) - Anx ety Score	HADS part c pant rated quest onna re w th 2 subsca es HADS-A assesses state of genera zed anx ety (anx ous mood, rest essness, anx ous thoughts, pan c attacks); HADS-D assesses state of ost nterest and d m n shed p easure response (ower ng of hedon c tone) Each subsca e compr sed of 7 tems w th range 0 (no presence of anx ety or depress on) to 3 (severe fee ng of anx ety or depress on) Tota score 0 to 21 for each subsca e; h gher score nd cates greater sever ty of anx ety and depress on symptoms	Base ne, Week 12 and Week 24
Change From Base ne n the Hosp ta Anx ety and Depress on Sca e (HADS) - Depress on Score	HADS part c pant rated quest onna re w th 2 subsca es HADS-A assesses state of genera zed anx ety (anx ous mood, rest essness, anx ous thoughts, pan c attacks); HADS-D assesses state of ost nterest and d m n shed p easure response (ower ng of hedon c tone) Each subsca e compr sed of 7 tems w th range 0 (no presence of anx ety or depress on) to 3 (severe fee ng of anx ety or depress on) Tota score 0 to 21 for each subsca e; h gher score nd cates greater sever ty of anx ety and depress on symptoms	Base ne, Week 12 and Week 24
Work Product v ty and Act v ty mpa rment Psor as s (WPA PSO) at Week 12	WPA PSO - part c pant rated quest onna re to assess effect of psor as s on ab ty to work and perform regu ar act v t es n 4 areas percent act v ty mpa rment (0 [no effect on da y act v t es] to 100 [psor as s comp ete y prevented from do ng da y act v t es]), percent mpa rment wh e work ng (0 [no effect] to 100 [comp ete y prevented from work ng]); percent work t me m ssed due to psor as s, and percent overa work mpa rment (0 [no effect] to 100 [comp ete y prevented from work ng])	Week 12

Work Product v ty and Act v ty mpa rment Psor as s (WPA PSO) at Week 24	WPA PSO - part c pant rated quest onna re to assess effect of psor as s on ab ty to work and perform regu ar act v t es n 4 areas percent act v ty mpa rment (0 [no effect on da y act v t es] to 100 [psor as s comp ete y prevented from do ng da y act v t es]), percent mpa rment wh e work ng (0 [no effect] to 100 [comp ete y prevented from work ng]); percent work t me m ssed due to psor as s, and percent overa work mpa rment (0 [no effect] to 100 [comp ete y prevented from work ng])	Week 24
Mean Med ca Outcomes Study (MOS) S eep Sca e Scores at Week 12	MOS sca e has 12 quest ons to assess s eep qua ty & quant ty 1)t me to fa as eep, 2)hours of s eep/n ght n past 4 weeks,3)s eep not peacefu , 4)got enough s eep to fee rested n morn ng,5)awaken short of breath/headache 6)fee drowsy n day,7)troub e go ng to s eep, 8)wake up dur ng s eep; troub e go ng back to s eep,9)troub e stay ng awake n day, 10)Snor ng,11)take naps n day,12)get amount of s eep needed S eep prob em ndex(SP) mean of 4,5,7,8,9,12; SP mean of 1,3,4,5,6,7,8,9,12 A reported responses are on sca e 0-100, h gher scores nd cate greater ntens ty of attr bute	Week 12
Mean Med ca Outcomes Study (MOS) S eep Sca e Scores at Week 24	MOS part c pant rated quest onna re to assess s eep qua ty and quant ty Cons sts of a 9- tem overa s eep prob ems ndex (ength of t me to fa as eep, how many hours of s eep each n ght dur ng past 4 weeks); 7 subsca es rated 1 (a the t me) to 6 (none of the t me) s eep d sturbance, snor ng, awaken short of breath (SOB) or w th headache, somno ence adequacy, and s eep quant ty Scores are transformed (actua raw score m nus owest poss b e score d v ded by poss b e raw score range mu t p ed by 100); tota score range = 0 to 100; h gher score nd cates greater ntens ty of attr bute	Week 24
Mean Funct ona Assessment of Chron c ness Therapy (FAC T) Fat gue Quest onna re Tota Scores	FAC T Fat gue quest onna re Part c pant rated 13 tems quest onna re to assess fat gue For each quest on, part c pant rates h s / her cond t on for the past week on a 5-po nt L kert sca e rang ng from 0 (not at a) to 4 (very much) H gher scores a ways represent ess fat gue The tota FAC T-Fat gue score ranges from 0 to 52 and s the sum of non-m ss ng tem scores; d v ded by the number of non-m ss ng tems, then mu t p ed by 13 f more than 6 tems were m ss ng, the tota score was m ss ng	Week 12 and Week 24
Percentage of Part c pants W th Emergency Room V s ts	As a part of pharmacoeconom c quest onna re, the v s ts to emergency room were eva uated and presented as Yes or No	Week 12 and Week 24
Mean Number of Emergency Room Days	As a part of pharmacoeconom c quest onna re, mean number of emergency room days were summar zed	Week 12 and Week 24
Percentage of Part c pants W th Doctor V s ts	As a part of pharmacoeconom c quest onna re, the percentage of part c pants who had doctor v s ts were presented as Yes or No	Week 12 and Week 24
Mean Number of Doctor V s ts	As a part of pharmacoeconom c quest onna re, the mean number of doctor v s ts were summar zed	Week 12 and Week 24

Collaborators and Investigators

Th s s where you w find peop e and organ zat ons nvo ved w th th s study

Sponsor

Pfizer

Collaborators

No nformat on prov ded

Investigators

- Study D rector Pfizer CT gov Ca Center, Pfizer

Publications

The person respons b e for enter ng nformat on about the study vo untar y prov des these pub cat ons These may be about anyth ng re ated to the study

General Publications

No pub cat ons ava ab e

* Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.

Study Record Dates

These dates track the progress of study record and summary resu ts subm ss ons to C n ca Tr a s gov Study records and reported resu ts are rev ewed by the Nat ona L brary of Med c ne (NLM) to make sure they meet spec fic qua ty contro standards before be ng posted on the pub c webs te

Study Registration Dates

First Submitted
2008-04-17

First Submitted that Met QC Criteria
2008-04-17

First Posted (Estimated)
2008-04-21

Results Reporting Dates

Results First Submitted
2011-01-18

Results First Submitted that Met QC Criteria
2012-03-29

Results First Posted (Estimated)
2012-04-23

Study Record Updates

Last Update Submitted that met QC Criteria
2012-03-29

Last Update Posted (Estimated)
2012-04-23

Last Verified
2012-03

More Information

Terms related to this study

Keywords Provided by Pfizer

Enbre
Psor as s
Top ca Psor as s
Wyeth Psor as s
Act ve Psor as s

Additional Relevant MeSH Terms

Sk n D seases, Papu osquamous
Sk n D seases
Psor as s
Ant nflammatory Agents, Non Stero da
Ana ges cs, Non Narcot c
Ana ges cs
Sensory System Agents
Per phera Nervous System Agents
Phys o og ca Effects of Drugs
Ant nflammatory Agents
Ant rheumat c Agents
Gastro ntest na Agents
mmunosuppress ve Agents
mmuno og c Factors
Etanercept

Drug and device information, study documents, and helpful links

Study Documents

No study documents ava ab e

Helpful Links Provided by Pfizer

To obta n contact nformat on for a study center near you, c ck here (https //tr a nfoema pfizer com/pages/ and ng aspx?Study D=0881A6 4425&StudyName=Study%20Eva uat ng%20Etanercept%20for%20the%20Treatment%20of%20Moderate%20to%20Severe%20Psor as s)

Record 1 of 1

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Preference Between Two Autoinjectors in Patients With Rheumatoid Arthritis and Plaque Psoriasis Treated With Etanercept

ClinicalTrials.gov ID NCT01875991

Sponsor Amgen

Information provided by Amgen (Responsible Party)

Last Update Posted 2018 09 04

Study Details Tab

Study Overview

Brief Summary

The study will estimate the preference of rheumatoid arthritis (RA) and Plaque Psoriasis (PsO) patients who self inject etanercept for one of two experimental autoinjectors.

Feedback

Detailed Description

Candidates for treatment are those who in the determination of the investigator s standard of care and the caring physician s intent are to initiate treatment with etanercept. Participants must be naïve to etanercept and naïve to other autoinjector pens or prefilled syringes and be able to self inject. The study will consist of a 30 day screening period, and 2 treatment periods of 4 weeks duration each (one treatment period using Autoinjector A and the other using Autoinjector B). At the end of the study, participants may continue treatment with commercially available etanercept at the physician s discretion.

Official Title

An Open label, Randomized, Crossover Study to Assess the Preference for Autoinjector A Versus Autoinjector B in Rheumatoid Arthritis and Plaque Psoriasis Subjects Treated With Etanercept

Conditions

Rheumatoid Arthritis | Plaque Psoriasis

Intervention / Treatment

- Drug: Etanercept via Autoinjector A
- Drug: Etanercept via Autoinjector B

Other Study ID Numbers

- 20090176

Study Start (Actual)

2013 06 05

Primary Completion (Actual)

2014 03 04

Study Completion (Actual)

2014 03 04

Enrollment (Actual)

217

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus Genetics (https://medlineplus.gov/genetics/) related topics: Rheumatoid arthritis (https://medlineplus.gov/genetics/condition/rheumatoid arthritis)

MedlinePlus (https://medlineplus.gov/) related topics: Arthritis (https://medlineplus.gov/arthritis.html) Psoriasis (https://medlineplus.gov/psoriasis.html) Rheumatoid Arthritis (https://medlineplus.gov/rheumatoidarthritis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Etanercept (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Etanercept)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Alabama Locations

Huntsville, Alabama, United States, 35801
Research Site

Tuscaloosa, Alabama, United States, 35406
Research Site

Arizona Locations

Glendale, Arizona, United States, 85304

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria: Diagnosis of moderate to severe Rheumatoid Arthritis (RA) or moderate to severe Plaque Psoriasis (PsO) and a candidate for treatment with etanercept in the opinion of the investigator in addition to the caring physicians intent to initiate treatment with etanercept. Naive to etanercept. Naive to other autoinjector pens or prefilled syringes for Tumor Necrosis Factor (TNF) inhibitor therapy or other subcutaneous biologics for RA. Willing to self inject per investigator judgement at screening and capable of self injection using the autoinjector A or B as documented at baseline by the investigator. Able to read and write in English.

Exclusion Criteria: Latex allergy. Subject has an active infection (including chronic or localized infections) for which anti infectives were indicated within 4 weeks prior to first dose of etanercept. Subject had prosthetic joint infection within 5 years of screening or native joint infection within 1 year of screening.

- Other criteria may apply.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Crossover Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Autoinjector A Participants self-injected 50 mg etanercept once a week (RA) or twice a week (PsO) using Autoinjector A for 4 weeks.	Drug: Etanercept via Autoinjector A • Autoinjector A is a hand-held, reusable, electromechanical device used with a single-use disposable cassette preassembled with an etanercept 50-mg prefilled syringe.
Experimental: Autoinjector B Participants self-injected 50 mg etanercept once a week (RA) or twice a week (PsO) using Autoinjector B for 4 weeks.	Drug: Etanercept via Autoinjector B • Autoinjector B is a single-use, spring-loaded, self-contained autoinjector preassembled with an etanercept 50-mg prefilled syringe. • Other Names: ◦ Enbrel® SureClick®

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With a Preference for Autoinjector A Versus Autoinjector B	Preference for autoinjector A versus autoinjector B was assessed by Question 1 of the Subject Preference Questionnaire administered after the completion of the 2 treatment periods at Week 8. Participants answered the question "Which autoinjector do you prefer overall?"	Week 8

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Baseline in Needle Apprehension at Week 4	Participants needle apprehension was assessed using the Subject s Perception of Self-Injecting Questionnaire. Participants answered the question "Overall how nervous are you about the needle when you think about giving yourself etanercept using the autoinjector" using a scale from 1 (extremely nervous) to 5 (not at all nervous).	Baseline and Week 4
Ease of Use	Ease of use was assessed based on responses to questions 1 to 6 of the Subject s Experience with the Autoinjector Questionnaire: 1. How easy was it to learn how to use the autoinjector? 2. How easy was it for you to press the button to start the injection? 3. How easy was the autoinjector to use? 4. How easy was it to hold the autoinjector throughout the injection? 5. How easy was it for you to inject yourself using the autoinjector? 6. How easy was it to follow the progress of the injection? Each question was answered on a scale from 1 (Very difficult) to 5 (Very easy). The percentage of participants	At the end of each treatment period; Week 4 and Week 8

	who scored either a 4 (Somewhat easy) or 5 (Very easy) on each question is reported.	
Certainty of Completing the Injection With the Autoinjector	Certainty of completing the injection with the autoinjector was assessed based on responses to Question 7 of the Subject s Experience with the Autoinjector Questionnaire: "How certain were you that you knew when the injection was finished?" Participants answered on a scale from 1 (Not at all) to 5 (Extremely). The percentage of participants who scored 4 (Very) or 5 (Extremely) is reported.	At the end of each treatment period; Week 4 and Week 8
Convenience	Convenience was assessed based on responses to Question 8 of the Subject s Experience with the Autoinjector Questionnaire: "How convenient was the autoinjector to use?" Participants answered on a scale from 1 (Not at all) to 5 (Very much). The percentage of participants who scored a 4 (Quite a bit) or 5 (Very much) is reported.	At the end of each treatment period; Week 4 and Week 8
Discomfort	Discomfort was assessed based on responses to Question 9 of the Subject s Experience with the Autoinjector Questionnaire: "How much discomfort did you experience when giving yourself the medicine using the autoinjector?" Participants answered on a scale from 1 (None) to 5 (Very much). The percentage of participants who scored a 1 (None) or 2 (A little) is reported.	At the end of each treatment period; Week 4 and Week 8

Satisfaction	Satisfaction was assessed based on responses to questions 11 and 12 of the Subject s Experience with the Autoinjector Questionnaire. Question 11: "How dependable (durable, sturdy, reliable) did you feel the autoinjector device was?" answered on a scale from 1 (Not at all) to 5 (Very much). Question 12: "Overall, how likely would you be to recommend the autoinjector to someone like you who is on etanercept?" answered on a scale from 1 (Would not recommend) to 5 (Highly likely to recommend). The percentage of participants who scored either a 4 or 5 on each question is reported.	At the end of each treatment period; Week 4 and Week 8
Pain Associated With Use of the Autoinjector	Pain associated with use of the autoinjector was assessed based on responses to Question 10 of the Subject s Experience with the Autoinjector Questionnaire: "Using this scale, select the circle that best describes how much it hurt when giving yourself an injection." Participants answered on a scale from 0 (No hurt) to 5 (Hurts worst). The percentage of participants who scored a 0 (No hurt) or 1 (Hurts a little bit) is reported.	At the end of each treatment period; Week 4 and Week 8
Strength of Preference for Autoinjector A and Autoinjector B	Strength of preference for Autoinjector A versus Autoinjector B was assessed by Question 2 of the Subject Preference Questionnaire administered after the completion of the two treatment periods at Week 8. After selecting which autoinjector they preferred overall, participants were asked to indicate how much they preferred it on a scale from 1 (Slightly), 2 (Somewhat), 3 (Strongly) and 4 (Vey Strongly).	Week 8

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Amgen

Collaborators

No information provided

Investigators

- Study Director: MD, Amgen

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2013-06-10

First Submitted that Met QC Criteria
2013-06-10

First Posted (Estimated)
2013-06-12

Results Reporting Dates

Results First Submitted
2015-03-03

Results First Submitted that Met QC Criteria
2015-05-01

Results First Posted (Estimated)
2015-05-20

Study Record Updates

Last Update Submitted that met QC Criteria
2018-08-01

Last Update Posted
2018-09-04

Last Verified
2018-08

More Information

Terms related to this study

Additional Relevant MeSH Terms

Joint Diseases
Musculoskeletal Diseases
Rheumatic Diseases

Connective Tissue Diseases
Autoimmune Diseases
Immune System Diseases
Skin Diseases, Papulosquamous
Skin Diseases
Arthritis
Arthritis, Rheumatoid
Psoriasis
Anti Inflammatory Agents, Non Steroidal
Analgesics, Non Narcotic
Analgesics
Sensory System Agents
Peripheral Nervous System Agents
Physiological Effects of Drugs
Anti Inflammatory Agents
Antirheumatic Agents
Gastrointestinal Agents
Immunosuppressive Agents
Immunologic Factors
Etanercept

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by Amgen

AmgenTrials clinical trials website (http://www.amgentrials.com)

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

The U.S. government does not review or approve the safety and science of all studies listed on this website.

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ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

A Study of Efalizumab in Participants With Moderate to Severe Chronic Psoriasis Who Have Failed, Have a Contraindication to, or Are Intolerant of Other Systemic Therapies

ClinicalTrials.gov ID **NCT00249808**

Sponsor Merck KGaA, Darmstadt, Germany

Information provided by Merck KGaA, Darmstadt, Germany (Responsible Party)

Last Update Posted 2018 03 20

Study Details Tab

Study Overview

Brief Summary

Feedback

This is a Phase IIIb/IV, open label, multicentre study of efalizumab (anti cluster of differentiation [CD] 11a recombinant human monoclonal antibody) in participants with moderate to severe plaque psoriasis who have failed to respond to, have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate, and psoralen and ultraviolet A phototherapy (PUVA).

Official Title

A Multicentre, Open Label Phase IIIb/IV Study of Subcutaneously Administered Efalizumab in the Treatment of Adult Patients With Moderate to Severe Chronic Plaque Psoriasis Who Have Failed to Respond to, or Who Have a Contraindication to, or Are Intolerant to Other Systemic Therapies Including Ciclosporin, Methotrexate and PUVA

Conditions

Psoriasis

Intervention / Treatment

- Drug: Efalizumab anti CD11a recombinant human monoclonal antibody

Other Study ID Numbers

- 25300
- Control II Study

Study Start (Actual)

2004 12 13

Primary Completion (Actual)

2007 01 25

Study Completion (Actual)

2007 01 25

Enrollment (Actual)

1266

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United Kingdom

Feltham, United Kingdom
Medical Information

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Moderate to severe plaque psoriasis participants who have failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including cyclosporine, methotrexate and PUVA
- Age at least 18 years
- For women of childbearing potential and for men whose partner can become pregnant, use of an acceptable method of contraception to prevent pregnancy and agreement to continue to practice an acceptable method of contraception for the duration of their participation in the study and up to 3 months after the last dose of efalizumab
- Have given written informed consent, prior to any study related procedure not part of normal medical care, with the understanding that consent may be withdrawn by the participant at any time without prejudice to future medical care
- Discontinuation of any systemic psoriasis treatment prior to commencement of the study drug. No washout period is required for these agents prior to starting study and receiving first dose of study drug (efalizumab)
- Discontinuation of all biologic agents (other than efalizumab) 3 months prior to receiving first dose of study drug (efalizumab)
- Discontinuation of any investigational drug or treatment 3 months prior to Study Day 0 or as per washout requirements from previous protocol
- No primary vaccinations (e.g., tetanus, booster, influenza vaccine) at least 14 days prior to first dose of study drug
- The participant must be willing and able to comply with the protocol requirements for the duration of the study

Exclusion Criteria:

- Guttate, erythrodermic, or pustular psoriasis as sole or predominant form of psoriasis
- Participants who have previously been on efalizumab treatment who withdrew due to lack of efficacy or an adverse event. If withdrawal was due to another non drug reason (vaccination, or infection) then the patient can be included in this study
- History of severe allergic or anaphylactic reactions to humanised monoclonal antibodies
- History of or ongoing uncontrolled bacterial, viral, fungal, or atypical mycobacterial infection
- History of opportunistic infections (eg, systemic fungal infections, parasites)
- Seropositivity for human immunodeficiency virus (HIV). Participants will undergo mandatory testing at screening. Participants who are positive for HIV will be excluded
- Pregnancy or breast feeding
- White Blood Cell (WBC) count less than (<) 4*10^9 per liter or greater than (>) 14*10^9 per liter
- Participants with a history of clinically significant thrombocytopenia, bleeding disorders or a platelet count <100*10^9 per liter
- Seropositivity for hepatitis B or C virus. Participants will undergo testing at screening. Participants who are positive for hepatitis B antigen or hepatitis C antibody will be

excluded

- History of active tuberculosis (TB) or currently undergoing treatment for TB within one year prior to Study Day 0. Chest X ray (within 3 months prior to Study Day 0) is required for high risk participants. Participants with a positive chest X ray will be excluded
- Presence of malignancy within the past 5 years, including lymphoproliferative disorders. Participants with a history of fully resolved basal cell or squamous cell skin cancer may be enrolled
- Hospital admission for cardiac disease, stroke, or pulmonary disease within the last year
- Any medical condition that, in the judgment of the investigator, would jeopardize the participant s safety following exposure to study drug

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : N/A
Interventional Model : Single Group Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Efalizumab	Drug: Efalizumab - anti-CD11a recombinant human monoclonal antibody • Participants will receive efalizumab 1.0 milligram per kilogram (mg/kg) (with an initial conditioning dose of 0.7 mg/kg) once weekly by subcutaneous injection for 12 weeks (first treatment [FT]). Depending on the response at Week 12, participants could receive additional 8 to 12 weekly injections of efalizumab 1.0 mg/kg.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With Physician s Global Assessment (PGA) Ratings of Good or Better (FT)	The PGA assesses the global response of all psoriatic lesions to therapy by comparing the participant s present condition to baseline. PGA response includes: Cleared (100 percent [%] improvement; remission of all clinical signs and symptoms, except for residual manifestations such as mild erythema); Excellent (75% to 99% improvement of all clinical signs and symptoms, except for residual manifestations such as mild erythema); Good (50% to 74% improvement of all clinical signs and symptoms); Fair (25% to 49% improvement of all clinical signs and symptoms); Slight (1% to 24% improvement of all clinical signs and symptoms); Unchanged (clinical signs and symptoms unchanged); Worse (clinical signs	Week 12

	and symptoms deteriorated). Percentage of participants with PGA ratings of Good or Better (i.e, Good, Excellent or Cleared) are reported.	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With Psoriasis Rebound	Rebound was defined as worsening of disease as assessed by Psoriasis Area and Severity Index (PASI) score >125% of baseline or new pustular, erythrodermic, or more inflammatory psoriasis occurring within 2 months of stopping therapy. PASI is an instrument used to assess the extent of cutaneous psoriasis and to measure the effects of therapy. The PASI divides the body into four anatomical regions: head, trunk, upper limbs, and lower limbs. For each region, the evaluator assesses the severity of erythema, induration/thickness and scaling and determines the percentage of the region affected by disease. A numerical PASI score is derived that evaluates the severity of symptoms in terms of the total body surface area affected. Total PASI score ranges from 0 to 72, with higher scores indicating more severe disease.	Up to 8 weeks after end of FT (up to Week 20)
Percentage of Participants With Psoriasis Exacerbation	Exacerbation was defined as disease worsening either during or after treatment which was more inflammatory in nature compared to baseline and occurred either within pre-existing plaques, at previously uninvolved sites, or as new morphologies of disease.	During study (40 weeks)

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Merck KGaA, Darmstadt, Germany

Collaborators

No information provided

Investigators

- Study Director: Medical Responsible, Merck KGaA, Darmstadt, Germany

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2005-11-04

First Submitted that Met QC Criteria
2005-11-04

First Posted (Estimated)
2005-11-07

Results Reporting Dates

Results First Submitted
2017-08-24

Results First Submitted that Met QC Criteria
2017-08-24

Results First Posted
2018-03-20

Study Record Updates

Last Update Submitted that met QC Criteria
2017-08-24

Last Update Posted
2018-03-20

Last Verified
2017-08

More Information

Terms related to this study

Keywords Provided by Merck KGaA, Darmstadt, Germany

Candidates for systemic therapy for psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Immunologic Factors
Physiological Effects of Drugs
Antibodies
Antibodies, Monoclonal

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

TERMINATED

The study was terminated after the European Medicines Agency recommended to suspend the marketing authorisation of Raptiva in the European Union

ChangE From Any Systemic psoriasiS therapY to Raptiva (EASY)

ClinicalTrials.gov ID NCT00697593

Sponsor Merck KGaA, Darmstadt, Germany

Information provided by Merck KGaA, Darmstadt, Germany

Last Update Posted 2014 02 13

Study Details Tab

Study Overview

Brief Summary

Feedback

To assess the safety of transitioning subjects to Raptiva therapy from standard oral systemic or phototherapy by overlapping with Raptiva whilst tapering the initial systemic therapy or phototherapy dose.

Official Title

A Phase IV Open Label Study in Moderate to Severe Chronic Plaque Psoriasis Subjects Transitioning From Previous Systemic Antipsoriasis Therapies (Methotrexate, Cyclosporine, Retinoids or Psoralen Ultraviolet Light A (PUVA), Narrow Band Ultraviolet Light B (NBUVB) to Raptiva 1mg/kg/ Week Therapy.

Conditions

Chronic Plaque Psoriasis

Intervention / Treatment

- Drug: Efalizumab anti CD11a recombinant human monoclonal antibody (mAb)

Other Study ID Numbers

- 27809

Study Start

2008 01

Primary Completion (Actual)

2009 04

Study Completion (Actual)

2009 04

Enrollment (Actual)

70

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard)
resources: Chronic Graft Versus Host Disease
(https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Canada

Ontario Locations

City Waterloo, Ontario, Canada, N2J 1C4
Probity Medical Research

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

1. Are at least 18 years old.
2. Have plaque psoriasis with an sPGA score of at least moderate or severe at time of initiation of previous systemic treatment.
3. Are transitioning from methotrexate, cyclosporine, retinoids, PUVA or NBUVB and initiating treatment with Raptiva according to the decision of the investigator and in accordance with the indication and the recommendations of the Raptiva Investigator Brochure, i.e. to which they have failed to respond, have a contraindication to or are intolerant of other systemic therapies.
4. Agree to participate in the study, and to disclose any medical events to the investigator. The subject must be willing and able to comply with the protocol requirements for the duration of the study.
5. Have given written informed consent with the understanding that consent may be withdrawn at any time without prejudice to future medical care.
6. Women of childbearing potential must use appropriate contraception during treatment and up to the last study visit (safety follow up visit). For men, it is also mandatory to practice contraception during participation in the trial, as there are no existing data on the effect of Raptiva on spermatogenesis.
7. Discontinuation of any investigational drug or treatment 3 months prior to study start or as per washout requirements from previous protocol.

No primary vaccinations (e.g., tetanus, booster, influenza vaccine) for at least 14 days prior to first dose of study drug.For the purposes of this trial, women of childbearing potential is defined as: "All female subjects after puberty unless they are post menopausal for at least two years, are surgically sterile or are sexually inactive."

Exclusion Criteria:

1. Any contra indication to Raptiva, according to the Investigator Brochure, or as follows:
    - Hypersensitivity to Raptiva or to any of the excipients.
    - Subjects with history of malignancies.
    - History of active tuberculosis (TB) or currently undergoing treatment for TB. Purified Protein Derivative (PPD) testing or chest X ray is required for high risk subjects. Subjects with a positive PPD (not due to BCG vaccination) or chest X ray will be excluded.
    - Subjects with specific forms of psoriasis like guttate, erythrodermic or pustular psoriasis as sole or predominant form of psoriasis.
    - Subjects with immunodeficiencies.
2. Simultaneous participation in another clinical trial.
3. Subjects experiencing a psoriasis exacerbation during screening period.
4. Subjects who have previously been on Raptiva treatment who withdrew due to lack of efficacy or an adverse event. If withdrawal was due to another non drug reason (vaccination, or infection) then the subject can be included in this study.

5. History of hepatitis B, hepatitis C or human immunodeficiency virus (HIV).
6. History of thrombocytopenia, haemolytic anaemia or clinically significant anaemia.
7. Hepatic enzyme levels =/>3 times the upper limit of normal or serum creatinine level =/>2 times the upper limit of normal.
8. Pregnant or breast feeding.
9. Any medical condition (prior or existing) that, in the judgment of the investigator or sponsor, could jeopardize the subject s safety following exposure to study drug.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : N/A
Interventional Model : Single Group Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Efalizumab	Drug: Efalizumab - anti CD11a recombinant human monoclonal antibody (mAb) • Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1mg/kg/week for up to 12 weeks.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Hematology - Hematocrit	Blood samples were taken for clinical laboratory testing	Week 12 / Early Termination
Hematology - Hemoglobin	Blood samples were taken for clinical laboratory testing	Week 12 / Early Termination
Hematology - Red Blood Cell Count	Blood samples were taken for clinical laboratory testing	Week 12 / Early Termination
Hematology - White Blood Cell Count	Blood samples were taken for clinical laboratory testing	Week 12 / Early Termination
Hematology - Neutrophils	Blood samples were taken for clinical laboratory testing	Week 12 / Early

		Termination
Hematology - Eosinophils	Blood samples were taken for clinical laboratory testing	Week 12 / Early Termination
Hematology - Basophils	Blood samples were taken for clinical laboratory testing	Week 12 / Early Termination
Hematology - Monocytes	Blood samples were taken for clinical laboratory testing	Week 12 / Early Termination
Hematology - Lymphocytes	Blood samples were taken for clinical laboratory testing	Week 12 / Early Termination
Hematology - Platelet Count	Blood samples were taken for clinical laboratory testing	Week 12 / Early Termination
Biochemistry - Sodium	Blood samples were taken for clinical laboratory testing	Week 12 / Early Termination
Biochemistry - Potassium	Blood samples were taken for clinical laboratory testing	Week 12 / Early Termination
Biochemistry - Creatinine	Blood samples were taken for clinical laboratory testing	Week 12 / Early Termination
Biochemistry - Total Bilirubin	Blood samples were taken for clinical laboratory testing	Week 12 / Early Termination

Biochemistry - Aspartate Transaminase (AST)	Blood samples were taken for clinical laboratory testing	Week 12 / Early Termination
Biochemistry - Alanine Transaminase (ALT)	Blood samples were taken for clinical laboratory testing	Week 12 / Early Termination
Biochemistry - Alkaline Phosphatase	Blood samples were taken for clinical laboratory testing	Week 12 / Early Termination
Biochemistry - Glutamyl Transferase	Blood samples were taken for clinical laboratory testing	Week 12 / Early Termination
Biochemistry - Urea	Blood samples were taken for clinical laboratory testing	Week 12 / Early Termination
Biochemistry - C-Reactive Protein (CRP)	Blood samples were taken for clinical laboratory testing of the numbers of participants with CRP values <3 mg/L, 3-6 mg/L, and >6 mg/L	Week 12 / Early Termination
Urinalysis - pH	Urine samples were taken for clinical laboratory testing	Week 12 / Early Termination
Urinalysis - Protein	Urine samples were taken for clinical laboratory testing of the number of participants with or without protein in urine	Week 12 / Early Termination
Urinalysis - Ketones	Urine samples were taken for clinical laboratory testing of the number of	Week 12 / Early

	participants with or without ketones in urine	Termination
Urinalysis - Glucose	Urine samples were taken for clinical laboratory testing of the number of participants with or without glucose in urine	Week 12 / Early Termination
Urinalysis - Blood	Urine samples were taken for clinical laboratory testing of the number of participants with or without blood in urine	Week 12 / Early Termination
Urinalysis - Nitrite	Urine samples were taken for clinical laboratory testing of the number of participants with or without nitrite in urine	Week 12 / Early Termination
Urinalysis - Leukocytes Esterase	Urine samples were taken for clinical laboratory testing of the number of participants with or without leukocytes esterase in urine	Week 12 / Early Termination
Adverse Events, Serious Adverse Events, and Laboratory Data (Haematology and Biochemistry) and Urinalysis	Information on adverse events are displayed in the adverse events section. Information laboratory data and urinalysis findings are displayed individually above	Week 12 / Early Termination

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Static Physicians Global Assessment (sPGA)	Number of subjects who achieve an Static Physicians Global Assessment (sPGA) rating of clear; minimal; mild; moderate; severe; or very severe at Week 12 (Day 85).	12 Weeks/Early Termination

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Merck KGaA, Darmstadt, Germany

Collaborators

No information provided

Investigators

- Study Director: Nicole Selenko Gebauer, Merck Serono International S.A., an affiliate of Merck KGaA, Darmstadt, Germany

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted

2008-06-11

First Submitted that Met QC Criteria

2008-06-13

First Posted (Estimated)

2008-06-16

Results Reporting Dates

Results First Submitted

2010-06-29

Results First Submitted that Met QC Criteria

2010-08-04

Results First Posted (Estimated)

2010-08-30

Study Record Updates

Last Update Submitted that met QC Criteria

2014-01-20

Last Update Posted (Estimated)

2014-02-13

Last Verified

2014-01

More Information

Terms related to this study

Keywords Provided by Merck KGaA, Darmstadt, Germany

Efalizumab
Chronic Plaque Psoriasis
Transition from systemic therapies on to Efalizumab

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Immunologic Factors
Physiological Effects of Drugs
Antibodies
Antibodies, Monoclonal

Study Documents

No study documents available

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Record 1 of 1

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study-basics/learn-about-studies).

COMPLETED

A One-Year Study To Evaluate The Effects And Safety Of CP-690,550 In Patients With Moderate To Severe Chronic Plaque Psoriasis

ClinicalTrials.gov ID NCT01276639

Sponsor Pfizer

Information provided by Pfizer (Responsible Party)

Last Update Posted 2014-09-19

Study Details Tab

Study Overview

Brief Summary

The main objective of this study is to compare the effects of CP-690,550 with the effects of placebo in patients being treated for moderate to severe chronic plaque psoriasis. This one-year study will also evaluate the safety and tolerability of CP-690,550 versus placebo.

Official Title

Phase 3 Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Of The Efficacy And Safety Of 2 Ora Doses Of CP-690,550 In Subjects With Moderate To Severe Chronic Plaque Psoriasis

Feedback

Conditions

Psoriasis

Intervention / Treatment

- Drug: CP-690,550
- Drug: CP-690,550
- Drug: Placebo/CP-690,550
- Drug: Placebo/CP-690,550

Other Study ID Numbers

- A3921078

Study Start

2011-03

Primary Completion (Actual)

2013-04

Study Completion (Actual)

2013-04

Enrollment (Actual)

901

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic-graft-versus-host-disease)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Alabama Locations

Birmingham, Alabama, United States, 35209
Rad ant Research, nc

California Locations

Irvine, California, United States, 92697
Un vers ty of Ca forn a, rv ne - Dermato ogy Research

San Diego, California, United States, 92117

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study-basics/learn-about-studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Are 18 years or older with diagnosis for at least 12 months of moderate to severe plaque psoriasis covering as least 10%of body surface area
- a Psoriasis Area and Severity Index (PASI) score of 12 and are considered to be candidates for systemic or light therapy
- No evidence of active or latent tuberculosis

Exclusion Criteria:

- Non-plaque or drug induced forms of psoriasis
- cannot discontinue current oral, injectible or topical therapy for psoriasis or cannot discontinue phototherapy (PUVA or UVB)
- any uncontrolled significant medical condition

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Active Treatment 10 mg BID	Drug: CP 690,550 • 10 mg oral BID, Continuous treatment for 52 Weeks
Experimental: ActiveTreatment 5 mg BID	Drug: CP 690,550 • 5 mg oral BID, Continuous treatment for 52 Weeks
Placebo Comparator: Placebo Treatment	Drug: Placebo/CP 690,550 • 0 mg oral BID, Continuous treatment for 16 Weeks; 10 mg oral BID, Continuous Treatment for 36 Weeks (after completion of 16 Weeks of Placebo) Drug: Placebo/CP 690,550 • 0 mg oral BID, Continuous treatment for 16 Weeks; 5 mg oral BID, Continuous Treatment for 36 Weeks (after completion of 16 Weeks of Placebo)

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With Physician Global Assessment (PGA) of Psoriasis Score of Clear or Almost Clear at Week 16	The PGA of psoriasis is scored on a 5 point scale, reflecting a global consideration of the erythema, induration, and scaling across all psoriatic lesions. Average erythema, induration, and scaling are scored separately over the whole body according to a 5 point severity scale (0 [no symptom] to 4 [severe symptom]). The total score was calculated as average of the 3 severity scores and rounded to the nearest whole number score to determine the PGA score and category (0=clear; 1=almost clear; 2=mild; 3=moderate; and 4=severe). PGA response was defined as 0 (clear) or 1 (almost clear).	Week 16

Percentage of Participants With a Psoriasis Area and Severity Index 75 (PASI 75) Response at Week 16	The PASI quantifies the severity of a participant s psoriasis based on both, "lesion severity" and the "percent of body surface area (BSA)" affected. PASI is a composite scoring by the investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]), with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The PASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis. PASI 75 response was defined as at least a 75 percent (%) reduction in PASI relative to Baseline.	Week 16

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percent Change From Baseline in Total Body Surface Area (BSA) With Psoriasis at Week 16	Assessment of BSA with psoriasis was estimated by means of the handprint method, where the full palmar hand of the participant (fully extended palm, fingers and thumb together) represented approximately 1% of the total BSA. Body regions are assigned specific number of handprints with percentage [Head and neck = 10% (10 handprints), upper extremities = 20% (20 handprints), Trunk (including axillae and groin) = 30% (30 handprints), lower extremities (including buttocks) = 40% (40 handprints)]. The number of handprints of psoriatic skin in a body region was used to determine the extent (%) to which a body region was involved with psoriasis. The total BSA affected was the summation of individual regions affected.	Baseline, Week 16
Percentage of Participants With a Psoriasis Area and Severity Index 90 (PASI 90) Response at Week 16	The PASI quantifies the severity of a participant s psoriasis based on both, lesion severity and the percent of BSA affected. PASI is a composite scoring by the investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]), with adjustment for the percent of BSA involved for each	Week 16

	body region and for the proportion of the body region to the whole body. The PASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis. PASI 90 response was defined as at least a 90% reduction in PASI relative to Baseline.	
Dermatology Life Quality Index (DLQI) Total Score	The DLQI is a 10 item general dermatology questionnaire that assess health related quality of life (daily activities, personal relationships, symptoms and feelings, leisure, work and school, and treatment). The DLQI item response options are rated by the participant from 0 (not at all/not relevant) to 3 (very much) with a total score range of 0 (best) to 30 (worst); higher scores indicate poor quality of life.	Baseline
Change From Baseline in Dermatology Life Quality Index (DLQI) Total Score at Week 4 and 16	The DLQI is a 10 item general dermatology questionnaire that assess health related quality of life (daily activities, personal relationships, symptoms and feelings, leisure, work and school, and treatment). The DLQI item response options are rated by the participant from 0 (not at all/not relevant) to 3 (very much) with a total score range of 0 (best) to 30 (worst); higher scores indicate poor quality of life.	Week 4, 16
Percentage of Participants With Physician Global Assessment (PGA) of Psoriasis Score of Clear or Almost Clear at Week 4	The PGA of psoriasis is scored on a 5 point scale, reflecting a global consideration of the erythema, induration, and scaling across all psoriatic lesions. Average erythema, induration, and scaling are scored separately over the whole body according to a 5 point severity scale (0 [no symptom] to 4 [severe symptom]). The total score was calculated as average of the 3 severity scores and rounded to the nearest whole number score to determine the PGA score and category (0=clear; 1=almost clear; 2=mild; 3=moderate; and 4=severe). PGA response was defined as 0 (clear) or 1 (almost clear).	Week 4
Percentage of Participants With a Psoriasis Area and Severity Index 75 (PASI 75)	The PASI quantifies the severity of a participant s psoriasis based on both, lesion severity and the percent of BSA affected. PASI is a composite scoring by the investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including	Week 4

Response at Week 4	axillae and groin], and lower limbs [including buttocks]), with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The PASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis. PASI 75 response was defined as at least 75% reduction in PASI relative to Baseline.	
Percent Change From Baseline in Nail Psoriasis Severity Index (NAPSI) at Week 16	The NAPSI quantifies severity of nail psoriasis by evaluating the presence or absence of psoriatic manifestations on the nail matrix (pitting, leukonychia, red spots on lulunea, crumbling) and nail bed (onycholysis, splinter hemorrhages, subungual hyperkeratosis, oil drop [salmon patch dyschromia]). Each finger nail divided with imaginary lines into quadrants and scored for both nail matrix and nail bed psoriasis (range from 0 [absence of psoriasis] to 4 [presence of psoriasis in all 4 quadrants]). The total NAPSI score equals the sum of scores for all of the finger nails evaluated and ranges from 0 to 80. Higher scores = more severe psoriasis.	Baseline, Week 16
Percent Probability of Participants Maintaining Physician Global Assessment (PGA) of Psoriasis Score of Clear or Almost Clear at Week 52	The PGA of psoriasis is scored on a 5 point scale, reflecting a global consideration of the erythema, induration, and scaling across all psoriatic lesions. Average erythema, induration, and scaling are scored separately over the whole body according to a 5 point severity scale (0 [no symptom] to 4 [severe symptom]). The total score was calculated as average of the 3 severity scores and rounded to the nearest whole number score to determine the PGA score and category (0=clear; 1=almost clear; 2=mild; 3=moderate; and 4=severe). PGA response was defined as 0 (clear) or 1 (almost clear). Maintenance of PGA response at Week 52 among participants achieving PGA response at Week 16 is reported. Percent probability and 95% confidence interval (CI) were estimated based on the product limit estimator in survival analyses. Event is loss of response. Probability of maintaining response is (1 probability of loss of response).	Week 52
Percent Probability of Participants	The PASI quantifies severity of a participant s psoriasis based on both, lesion severity and percent of BSA	Week 52

Maintaining Psoriasis Area and Severity Index 75 (PASI 75) Response at Week 52	affected. PASI is a composite scoring by investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]), with adjustment for percent of BSA involved for each body region and for the proportion of the body region to the whole body. The PASI score range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis. PASI 75 response = at least 75% reduction in PASI relative to Baseline. Maintenance of PASI 75 response at Week 52 among participants achieving PASI 75 response at Week 16 is reported. Percent probability and 95% CI were estimated based on the product limit estimator in survival analyses. Event is loss of response. Probability of maintaining response is (1 probability of loss of response).	
Percent Probability of Participants Maintaining Psoriasis Area and Severity Index 90 (PASI 90) Response at Week 52	The PASI quantifies severity of a participant s psoriasis based on both, lesion severity and percent of BSA affected. PASI is a composite scoring by investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]), with adjustment for percent of BSA involved for each body region and for the proportion of the body region to the whole body. The PASI score range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis. PASI 90 response = at least 90% reduction in PASI relative to Baseline. Maintenance of PASI 90 response at Week 52 among participants achieving PASI 90 response at Week 16 is reported. Percent probability and 95% CI were estimated based on the product limit estimator in survival analyses. Event is loss of response. Probability of maintaining response is (1 probability of loss of response).	Week 52
Time to Achieve a Physician Global Assessment (PGA) of Psoriasis Score of Clear or Almost Clear	The PGA of psoriasis is scored on a 5 point scale, reflecting a global consideration of the erythema, induration, and scaling across all psoriatic lesions. Average erythema, induration, and scaling are scored separately over the whole body according to a 5 point severity scale (0 [no symptom] to 4 [severe symptom]). The total score was calculated as average of the 3	Baseline up to Week 16

	severity scores and rounded to the nearest whole number score to determine the PGA score and category (0=clear; 1=almost clear; 2=mild; 3=moderate; and 4=severe). PGA response was defined as 0 (clear) or 1 (almost clear). Median time to achieve a PGA response up to week 16 is reported. The median time to event was estimated based on the probability of event rate based on life table estimates (not the observed rate as in outcome measure 1). Median time to event is not estimable if the estimated probability of response by Week 16 is less than 50%.	
Time to Achieve Psoriasis Area and Severity Index 75 (PASI 75) Response	The PASI quantifies the severity of a participant s psoriasis based on both, "lesion severity" and "percent of BSA" affected. PASI is a composite scoring by the investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]), with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The PASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis. PASI 75 response was defined as at least 75% reduction in PASI relative to Baseline. The median time to event was estimated based on the probability of event rate based on life table estimates (not the observed rate as in outcome measure 2). Median time to event is not estimable if the estimated probability of response by Week 16 is less than 50%.	Baseline up to Week 16
Time to Achieve Psoriasis Area and Severity Index 50 (PASI 50) Response	The PASI quantifies the severity of a participant s psoriasis based on both, "lesion severity" and "percent of BSA" affected. PASI is a composite scoring by the investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]), with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The PASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis. PASI 50 response was defined as at least 50% reduction in PASI	Baseline up to Week 16

	relative to Baseline. The median time to event was estimated based on the probability of event rate based on life table estimates (not the observed rate as in outcome measure 26). Median time to event is not estimable if the estimated probability of response by Week 16 is less than 50%.	
Percentage of Participants With Physician Global Assessment (PGA) of Psoriasis Score of Clear or Almost Clear	The PGA of psoriasis is scored on a 5 point scale, reflecting a global consideration of the erythema, induration, and scaling across all psoriatic lesions. Average erythema, induration, and scaling are scored separately over the whole body according to a 5 point severity scale (0 [no symptom] to 4 [severe symptom]). The total score was calculated as average of the 3 severity scores and rounded to the nearest whole number score to determine the PGA score and category (0=clear; 1=almost clear; 2=mild; 3=moderate; and 4=severe). PGA response was defined as 0 (clear) or 1 (almost clear).	Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Percentage of Participants With Physician Global Assessment (PGA) of Psoriasis Score	The PGA of psoriasis is scored on a 5 point scale, reflecting a global consideration of the erythema, induration, and scaling across all psoriatic lesions. Average erythema, induration, and scaling are scored separately over the whole body according to a 5 point severity scale (0 [no symptom] to 4 [severe symptom]). The total score was calculated as average of the 3 severity scores and rounded to the nearest whole number score to determine the PGA score and category (0=clear; 1=almost clear; 2=mild; 3=moderate; and 4=severe). Percentage of participants with each PGA score is reported.	Baseline, Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Percentage of Participants Achieving Psoriasis Area and Severity Index 75 (PASI 75) Response	The PASI quantifies the severity of a participant s psoriasis based on both, "lesion severity" and "percent of BSA" affected. PASI is a composite scoring by the investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]), with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The PASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores	Week 2, 4, 8, 12, 16, 20, 28, 40, 52

	representing greater severity of psoriasis. PASI 75 response was defined as at least 75% reduction in PASI relative to Baseline. Percentage of participants with PASI 75 response is reported.	
Psoriasis Area and Severity Index (PASI) Score	The PASI quantifies the severity of a participant s psoriasis based on both, "lesion severity" and "percent of BSA" affected. PASI is a composite scoring by the investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]), with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The PASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis.	Baseline, Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Change From Baseline in Psoriasis Area and Severity Index (PASI) Score at Week 2, 4, 8, 12, 16, 20, 28, 40 and 52	The PASI quantifies the severity of a participant s psoriasis based on both, "lesion severity" and "percent of BSA" affected. PASI is a composite scoring by the investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]), with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The PASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis.	Baseline, Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Psoriasis Area and Severity Index (PASI) Component Scores	The PASI quantifies the severity of a participant s psoriasis based on both, "lesion severity" and the "percent of BSA" affected. Basic characteristics of psoriatic lesions: erythema, induration, and scaling (PASI components) are scored separately for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]) according to a 5 point scale: 0 (no involvement); 1 (slight); 2 (moderate); 3 (marked); 4 (very marked). PASI component score range from 0 to 4, where higher scores indicate greater severity of psoriatic lesions.	Baseline, Week 2, 4, 8, 12, 16, 20, 28, 40, 52

Change From Baseline in Psoriasis Area and Severity Index (PASI) Component Scores at Week 2, 4, 8, 12, 16, 20, 28, 40 and 52	The PASI quantifies the severity of a participant s psoriasis based on both, "lesion severity" and the "percent of body surface area (BSA)" affected. Basic characteristics of psoriatic lesions: erythema, induration, and scaling (PASI components) are scored separately for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]) according to a 5 point scale: 0 (no involvement); 1 (slight); 2 (moderate); 3 (marked); 4 (very marked). PASI component score range from 0 to 4, where higher scores indicate greater severity of psoriatic lesions.	Baseline, Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Percent Change From Baseline in Psoriasis Area and Severity Index (PASI) Score at Week 2, 4, 8, 12, 16, 20, 28, 40 and 52	The PASI quantifies the severity of a participant s psoriasis based on both, "lesion severity" and "percent of BSA" affected. PASI is a composite scoring by the investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]), with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The PASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis.	Baseline, Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Total Body Surface Area (BSA) With Psoriasis	Assessment of BSA with psoriasis was estimated by means of the handprint method, where the full palmar hand of the participant (fully extended palm, fingers and thumb together) represented approximately 1% of the total BSA. Body regions are assigned specific number of handprints with percentage [Head and neck = 10% (10 handprints), upper extremities = 20% (20 handprints), Trunk (including axillae and groin) = 30% (30 handprints), lower extremities (including buttocks) = 40% (40 handprints)]. The number of handprints of psoriatic skin in a body region was used to determine the extent (%) to which a body region was involved with psoriasis. The total BSA affected was the summation of individual regions affected.	Baseline, Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Percent Change From Baseline in Total Body Surface	Assessment of BSA with psoriasis was estimated by means of the handprint method, where the full palmar hand of the participant (fully extended palm, fingers and	Baseline, Week 2, 4, 8, 12, 16,

Area (BSA) With Psoriasis at Week 2, 4, 8, 12, 16, 20, 28, 40 and 52	thumb together) represented approximately 1% of the total BSA. Body regions are assigned specific number of handprints with percentage [Head and neck = 10% (10 handprints), upper extremities = 20% (20 handprints), Trunk (including axillae and groin) = 30% (30 handprints), lower extremities (including buttocks) = 40% (40 handprints)]. The number of handprints of psoriatic skin in a body region was used to determine the extent (%) to which a body region was involved with psoriasis. The total BSA affected was the summation of individual regions affected.	20, 28, 40, 52
Percentage of Participants With Psoriasis Area and Severity Index 50 (PASI 50) Response	The PASI quantifies the severity of a participant s psoriasis based on both, "lesion severity" and "percent of BSA" affected. PASI is a composite scoring by the investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]), with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The PASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis. PASI 50 response was defined as at least 50% reduction in PASI relative to Baseline. Percentage of participants with PASI 50 response is reported.	Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Percentage of Participants With Psoriasis Area and Severity Index 90 (PASI 90) Response	The PASI quantifies the severity of a participant s psoriasis based on both, "lesion severity" and "percent of BSA" affected. PASI is a composite scoring by the investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]), with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The PASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis. PASI 90 response was defined as at least 90% reduction in PASI relative to Baseline. Percentage of participants with PASI 90 response up to Week 52 is reported.	Week 2, 4, 8, 12, 16, 20, 28, 40, 52

Percentage of Participants With Psoriasis Area and Severity Index (PASI) Score of at Least 125% of Baseline PASI Score	The PASI quantifies the severity of a participant s psoriasis based on both, "lesion severity" and "percent of BSA" affected. PASI is a composite scoring by the investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]), with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The PASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis. Percentage of participants with PASI score of at least 125% of baseline PASI score are reported.	Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Nail Psoriasis Severity Index (NAPSI) Score	The NAPSI quantifies severity of nail psoriasis by evaluating the presence or absence of psoriatic manifestations on the nail matrix (pitting, leukonychia, red spots on lulunea, crumbling) and nail bed (onycholysis, splinter hemorrhages, subungual hyperkeratosis, oil drop [salmon patch dyschromia]). Each finger nail divided with imaginary lines into quadrants and scored for both nail matrix and nail bed psoriasis (range from 0 [absence of psoriasis] to 4 [presence of psoriasis in all 4 quadrants]). The total NAPSI score equals the sum of scores for all of the finger nails evaluated and ranges from 0 to 80. Higher scores = more severe psoriasis.	Baseline, Week 8, 16, 20, 28, 40, 52
Change From Baseline in Nail Psoriasis Severity Index (NAPSI) Score at Week 8, 16, 20, 28, 40 and 52	The NAPSI quantifies severity of nail psoriasis by evaluating the presence or absence of psoriatic manifestations on the nail matrix (pitting, leukonychia, red spots on lulunea, crumbling) and nail bed (onycholysis, splinter hemorrhages, subungual hyperkeratosis, oil drop [salmon patch dyschromia]). Each finger nail divided with imaginary lines into quadrants and scored for both nail matrix and nail bed psoriasis (range from 0 [absence of psoriasis] to 4 [presence of psoriasis in all 4 quadrants]). The total NAPSI score equals the sum of scores for all of the finger nails evaluated and ranges from 0 to 80. Higher scores = more severe psoriasis.	Baseline, Week 8, 16, 20, 28, 40, 52

Number of Affected Nails	Nail psoriasis is evaluated by the presence or absence of psoriatic manifestations on the nail matrix (pitting, leukonychia, red spots on lulunea, crumbling) and nail bed (onycholysis, splinter hemorrhages, subungual hyperkeratosis, oil drop [salmon patch dyschromia]). Total number psoriasis affected nails (presence of psoriatic manifestations on the nail matrix/nail bed) were assessed and reported.	Baseline, Week 8, 16, 20, 28, 40, 52
Percent Change From Baseline in Nail Psoriasis Severity Index (NAPSI) Score at Week 8, 16, 20, 28, 40 and 52	The NAPSI quantifies severity of nail psoriasis by evaluating the presence or absence of psoriatic manifestations on the nail matrix (pitting, leukonychia, red spots on lulunea, crumbling) and nail bed (onycholysis, splinter hemorrhages, subungual hyperkeratosis, oil drop [salmon patch dyschromia]). Each finger nail divided with imaginary lines into quadrants and scored for both nail matrix and nail bed psoriasis (range from 0 [absence of psoriasis] to 4 [presence of psoriasis in all 4 quadrants]). The total NAPSI score equals the sum of scores for all of the finger nails evaluated and ranges from 0 to 80. Higher scores = more severe psoriasis.	Baseline, Week 8, 16, 20, 28, 40, 52
Percentage of Participants With Nail Psoriasis Severity Index 75 (NAPSI 75) Response	The NAPSI quantifies severity of nail psoriasis by evaluating the presence or absence of psoriatic manifestations on the nail matrix (pitting, leukonychia, red spots on lulunea, crumbling) and nail bed (onycholysis, splinter hemorrhages, subungual hyperkeratosis, oil drop [salmon patch dyschromia]). Each finger nail divided with imaginary lines into quadrants and scored for both nail matrix and nail bed psoriasis (range from 0 [absence of psoriasis] to 4 [presence of psoriasis in all 4 quadrants]). The total NAPSI score equals the sum of scores for all of the finger nails evaluated and ranges from 0 to 80. Higher scores = more severe psoriasis. NAPSI 75 response was defined as at least a 75% reduction in NAPSI relative to Baseline. Percentage of participants with NAPSI 75 response is reported.	Week 8, 16, 20, 28, 40, 52
Percentage of Participants With Nail Psoriasis Severity Index 100	The NAPSI quantifies severity of nail psoriasis by evaluating the presence or absence of psoriatic manifestations on the nail matrix (pitting, leukonychia, red spots on lulunea, crumbling) and nail bed	Week 8, 16, 20, 28, 40, 52

(NAPSI 100) Response	(onycholysis, splinter hemorrhages, subungual hyperkeratosis, oil drop [salmon patch dyschromia]). Each finger nail divided with imaginary lines into quadrants and scored for both nail matrix and nail bed psoriasis (range from 0 [absence of psoriasis] to 4 [presence of psoriasis in all 4 quadrants]). The total NAPSI score equals the sum of scores for all of the finger nails evaluated and ranges from 0 to 80. Higher scores = more severe psoriasis. NAPSI 100 response was defined as at least a 100% reduction in NAPSI relative to Baseline. Percentage of participants with NAPSI 100 response is reported.	
Itch Severity Item (ISI) Score	ISI assessed severity of itch (pruritus) due to psoriasis. ISI is a single item, horizontal numeric rating scale. Participants were asked to rate "your worst itching due to psoriasis over the past 24 hours" on a numeric rating scale anchored by the terms "No itching" (0) and "Worst possible itching" (10) at the ends for post baseline time points. Baseline ISI is average of scores on 7 days prior to start of study treatment.	Baseline, Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Change From Baseline in Itch Severity Item (ISI) Score at Week 2, 4, 8, 12, 16, 20, 28, 40 and 52	ISI assessed severity of itch (pruritus) due to psoriasis. ISI is a single item, horizontal numeric rating scale. Participants were asked to rate "your worst itching due to psoriasis over the past 24 hours" on a numeric rating scale anchored by the terms "No itching" (0) and "Worst possible itching" (10) at the ends.	Baseline, Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Dermatology Life Quality Index (DLQI) Score	The DLQI is a 10 item general dermatology questionnaire that assess health related quality of life (daily activities, personal relationships, symptoms and feelings, leisure, work and school, and treatment). The DLQI item response options are rated by the participant from 0 (not at all/not relevant) to 3 (very much) with a total score range of 0 (best) to 30 (worst); higher scores indicate poor quality of life.	Baseline, Week 2, 4, 8, 12, 16, 20, 28, 40, 52
Change From Baseline in Dermatology Life Quality Index (DLQI) Score at	The DLQI is a 10 item general dermatology questionnaire that assess health related quality of life (daily activities, personal relationships, symptoms and feelings, leisure, work and school, and treatment). The DLQI item response options are rated by the participant from 0 (not at all/not relevant) to 3 (very much) with a total score	Baseline, Week 2, 4, 8, 12, 16, 20, 28, 40, 52

Week 2, 4, 8, 12, 16, 20, 28, 40 and 52	range of 0 (best) to 30 (worst); higher scores indicate poor quality of life.	
36 Item Short Form Health Survey Version 2, Acute (SF 36)	36 Item Short Form Health Survey (SF 36) is a standardized survey evaluating 8 aspects of functional health and well being: physical and social functioning, physical and emotional role limitations, bodily pain, general health, vitality, mental health. These 8 aspects are summarized as physical and mental health summary scores. The score range for the physical and mental health scores is 0 100 (100=highest level of functioning).	Baseline, Week 16, 28, 52
Hospital Anxiety and Depression Scale (HADS) Score	HADS: 14 item questionnaire that screens for the presence of anxiety and depression symptoms. There are 7 items comprising the anxiety subscale, and 7 items comprising the depression subscale. Each item has response option ranging from 0 (no presence of anxiety or depression) to 3 (severe feeling of anxiety or depression). Total score ranges from 0 to 21 for each subscale; higher score indicates greater severity of anxiety or depression symptoms.	Baseline, Week 4, 16, 28, 52
Work Limitation Questionnaire (WLQ) Index Score	WLQ: participant reported 25 item scale to evaluate degree to which health problems interfere with an ability to perform job roles along 4 dimensions: Time Management scale (5 items); Physical Demands scale (6 items); Mental Interpersonal Demands Scale (9 items); Output Demands Scale (5 items). All the scales ranged from 0 (limited none of the time) to 100 (limited all of the time). The WLQ Index score is the weighted sum of the scores from the 4 WLQ scales (total score: 0 [no loss] to 100 [complete loss of work]).	Baseline, Week 4, 16, 28, 52
Percentage of Participants With Patient Global Assessment (PtGA) Scale Response	The PtGA asks the participant to evaluate the overall cutaneous disease at that point in time on a single item, 5 point scale (0=clear [no psoriasis]; 1=almost clear; 2=mild; 3=moderate; 4=severe).	Baseline, Week 2, 4, 8, 12, 16, 20, 28, 40, 52

Percentage of Participants With Patient Satisfaction With Study Medication (PSSM) Score Response	The PSSM is a single, 7 point item that evaluates overall participant satisfaction with the study treatment. Response options range from "very dissatisfied" to "very satisfied" with the study treatment.	Week 16, 28, 52
Joint Pain Assessment (JPA) Score	The JPA assesses severity of joint pain. The JPA is a horizontal numeric rating scale. Participants were asked to "select the number that best describes any joint pain that participant may have experienced over the past 24 hours" with response options ranging from "0 no joint pain" to "10 worst possible joint pain."	Baseline, Week 4, 16, 28, 52
Euro Quality of Life 5 Dimensions (EQ 5D) Health State Profile Utility Score	EQ 5D: participant rated questionnaire to assess health related quality of life in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state ("confined to bed"). Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range 0.594 to 1.000; higher score indicates a better health state.	Baseline, Week 16, 28, 40, 52
Euro Quality of Life 5 Dimensions (EQ 5D) Visual Analog Scale (VAS)	EQ 5D: participant rated questionnaire to assess health related quality of life in terms of a single index value. The VAS component rates current health state on a scale from 0 millimeter (mm) (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state.	Baseline, Week 16, 28, 40, 52
Psoriasis Healthcare Resource Utilization Questionnaire (Ps HCRU) Interaction With Healthcare Professional	The Psoriasis Health Care Resource Utilization (Ps HCRU) questionnaire is a short questionnaire designed to assess healthcare resource use and the impact of psoriasis on work. The first section assesses direct costs associated with healthcare resource use (interactions with healthcare providers such as general practitioners, Dermatologist, Rheumatologist). Baseline is the latest pre dose measurement. Week 16 includes all reported log data to Week 16 (excluding Baseline). Participants may have response in more than 1 category.	Baseline, Week 16

	Data was not analyzed beyond Week 16 as per study teams decision because Week 0 16 period was considered sufficient to provide clear reflection of Ps HCRU endpoint.	
Psoriasis Healthcare Resource Utilization Questionnaire (Ps HCRU) Impact of Psoriasis on Work	The Psoriasis Health Care Resource Utilization (Ps HCRU) questionnaire is a short questionnaire designed to assess healthcare resource use and the impact of psoriasis on work. The second section assesses indirect costs associated with absenteeism due to psoriasis and the impact of psoriasis on productivity at work. Participants employed at the time of assessment answered (Yes/No [Y/N]): "Were you absent or on sick leave from work due to psoriasis today?", and participants unemployed (UEmp) at the time of assessment answered (Yes/No): "Are you unemployed due to your psoriasis?" Baseline is the latest pre dose measurement. Week 16 includes all reported log up to Week 16 (excluding Baseline). Data was not analyzed beyond Week 16 as per study teams decision because Week 0 16 period was considered sufficient to provide clear reflection of Ps HCRU endpoint.	Baseline, Week 16
Psoriasis Healthcare Resource Utilization Questionnaire (Ps HCRU) Healthcare Resource Use Events and Employment Status	The Psoriasis Health Care Resource Utilization (Ps HCRU) questionnaire is a short questionnaire designed to assess healthcare resource use and the impact of psoriasis on work. The first section assesses direct costs associated with healthcare resource use, and the second section assesses indirect costs associated with absenteeism due to psoriasis and the impact of psoriasis on productivity at work. Percentage of participants reporting healthcare resource use events and employment status, work impacted events due to psoriasis, and absence or sick leave for work due to psoriasis at Week 16 are reported. Data was not analyzed beyond Week 16 as per study teams decision because Week 0 16 period was considered sufficient to provide clear reflection of Ps HCRU endpoint.	Week 16
Psoriasis Healthcare Resource Utilization Questionnaire (Ps	The Psoriasis Health Care Resource Utilization (Ps HCRU) questionnaire is a short questionnaire designed to assess healthcare resource use and the impact of psoriasis on work. The first section assesses direct costs associated with healthcare resource use, and the	Baseline, Week 16

HCRU) Work Hours and Absent Hours	second section assesses indirect costs associated with absenteeism due to psoriasis and the impact of psoriasis on productivity at work. Baseline is the latest pre dose measurement. Participants reported hours scheduled to work and hours absent from work. Data was not analyzed beyond Week 16 as per study teams decision because Week 0 16 period was considered sufficient to provide clear reflection of Ps HCRU endpoint.	
Psoriasis Healthcare Resource Utilization Questionnaire (Ps HCRU) Percent Absent Hours	The Psoriasis Health Care Resource Utilization (Ps HCRU) questionnaire is a short questionnaire designed to assess healthcare resource use and the impact of psoriasis on work. The first section assesses direct costs associated with healthcare resource use, and the second section assesses indirect costs associated with absenteeism due to psoriasis and the impact of psoriasis on productivity at work. Baseline is the latest pre dose measurement. Participants reported hours scheduled to work and hours absent from work. Percent absent hours = (hours absent from work/hours scheduled to work) multiplied by 100. Data was not analyzed beyond Week 16 as per study teams decision because Week 0 16 period was considered sufficient to provide clear reflection of Ps HCRU endpoint.	Baseline, Week 16
Psoriasis Healthcare Resource Utilization Questionnaire (Ps HCRU) Psoriasis Affecting Ability to Work	The Psoriasis Health Care Resource Utilization (Ps HCRU) questionnaire is a short questionnaire designed to assess healthcare resource use and the impact of psoriasis on work. The first section assesses direct costs associated with healthcare resource use, and the second section assesses indirect costs associated with absenteeism due to psoriasis and the impact of psoriasis on productivity at work. Baseline is the latest pre dose measurement. Participants rate how much psoriasis affected their ability to work by reporting a number from 0 to 10, where 0 means "ability to work was not affected by psoriasis", and 10 means "ability to work was completely affected by psoriasis". Data was not analyzed beyond Week 16 as per study teams decision because Week 0 16 period was considered sufficient to provide clear reflection of Ps HCRU endpoint.	Baseline, Week 16

Family Dermatology Life Quality Index (FDLQI) Score	The FDLQI is a 10 item questionnaire that examine the impact of health related quality of life issues associated with living with a person with a skin condition (example, emotional distress, personal relationships, reactions of other people, social life, caregiving) over the last month. The FDLQI need to be completed by a family member (for example, spouse or partner, parent) who currently lives with the participant. Each question is scored on a scale from 0 (Not at all/ Not relevant) to 3 (Very much). Total score is calculated by summing the score of each item resulting in a maximum score of 30 and a minimum score of 0. Higher scores indicate greater impairment to quality of life.	Baseline, Week 16, 52

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Pfizer

Collaborators

No information provided

Investigators

- Study Director: Pfizer CT.gov Call Center, Pfizer

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2011 01 12

First Submitted that Met QC Criteria
2011 01 12

First Posted (Estimated)
2011 01 13

Results Reporting Dates

Results First Submitted
2014 07 24

Results First Submitted that Met QC Criteria
2014 09 18

Results First Posted (Estimated)
2014 09 19

Study Record Updates

Last Update Submitted that met QC Criteria
2014 09 18

Last Update Posted (Estimated)
2014 09 19

Last Verified
2014 09

More Information

Terms related to this study

Keywords Provided by Pfizer

Xeljanz
tofacitinib

chronic
Pruritus
Itch
DLQI
severe
moderate
treatment
safety
efficacy
CP-690,550
Plaque Psoriasis
Psoriasis Vulgaris
Jax-inhibitor
Oral Treatment

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Janus Kinase Inhibitors
Protein Kinase Inhibitors
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action
Tofacitinib

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by Pfizer

To obtain contact information for a study center near you click here.
(https://trialinfoemail.pfizer.com/pages/landing.aspx?StudyID_A3921078&StudyName_A%20One-Year%20Study%20To%20Evaluate%20The%20Effects%20And%20Safety%20Of%20CP-690%2C550%20In%20Patients%20With%20Moderate%20To%20Severe%20Chronic%20Plaque%20Psoriasis)

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ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

A Study of the Efficacy and Safety of DFD-06 Cream in the Treatment of Moderate to Severe Plaque Psoriasis

ClinicalTrials.gov ID **NCT02635204**

Sponsor Promius Pharma, LLC

Information provided by Promius Pharma, LLC (Responsible Party)

Last Update Posted 2018 05 15

Study Details Tab

Study Overview

Brief Summary

This study will compare the efficacy and safety of DFD 06 Cream to Vehicle Cream for topical treatment of moderate to severe plaque psoriasis after 3, 7, and 14 days of treatment.

Feedback

Detailed Description

This study will be a multicenter (approximately 30 sites), randomized, vehicle controlled, double blind, and parallel group design. Approximately 264 subjects with moderate to severe plaque psoriasis will be randomized to treatment with DFD 06 Cream or Vehicle Cream. Subjects will use study product twice daily for 14 days. Subject visits are scheduled at Screening, Baseline (Day 1) and Days 4, 8, and 15. Clinical determinations of disease severity will be performed using the total sign score (TSS) for the target lesion and Investigator Global Assessment (IGA) for overall severity.

Official Title

A Randomized, Double Blind, Vehicle Controlled, Multicenter, Parallel Group Study of the Efficacy and Safety of DFD 06 Cream in the Treatment of Moderate to Severe Plaque Psoriasis for 14 Days

Conditions

Psoriasis

Intervention / Treatment

- Drug: DFD06 Cream
- Drug: Vehicle Cream

Other Study ID Numbers

- DFD06 CD 004

Study Start

2015 12

Primary Completion (Actual)

2016 07

Study Completion (Actual)

2016 07

Enrollment (Actual)

267

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Clobetasol propionate (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Clobetasol+propionate)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Arizona Locations

Glendale, Arizona, United States, 85308
Site 116

Arkansas Locations

Rogers, Arkansas, United States, 72758
Site 111

California Locations

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

1. Subject understands the study procedures and agrees to participate by giving written informed consent. Subjects must be willing to authorize use and disclosure of protected health information collected for the study.
2. Subject must be at least 18 years of age.
3. Subject must present with a clinical diagnosis of stable (at least 3 months) plaque type psoriasis.
4. Subject with psoriasis involving 3% or greater BSA, not including the face, scalp, groin, axillae and other intertriginous areas.
5. Subject must have an IGA grade of 3 or 4 (moderate to severe) at the Baseline Visit.
6. Female subjects of childbearing potential must agree to use contraception during the study which can include abstinence with an adequate secondary option should the subject become sexually active. All women of childbearing potential must complete a urine pregnancy test (test must have a sensitivity of at least 25mIU/ml for human chorionic gonadotropin) at the Baseline Visit (Visit 2) and the test result must be negative to be eligible for enrollment.
7. Subject must be in good general health as determined by the investigator and supported by the medical history and normal or not clinically significant abnormal vital signs (blood pressure and pulse).

Exclusion Criteria:

1. Current diagnosis of unstable forms of psoriasis including guttate, erythrodermic, exfoliative or pustular psoriasis.
2. Other inflammatory skin disease that may confound the evaluation of the plaque psoriasis (e.g., atopic dermatitis, contact dermatitis, tinea corporis).
3. Presence of pigmentation, extensive scarring, or pigmented lesions or sunburn which could interfere with the rating of efficacy parameters.
4. History of psoriasis unresponsive to biological or topical treatments.
5. History of organ transplant requiring immunosuppression, HIV, or other immunocompromised state.
6. Use within 180 days prior to Baseline Visit of biologic treatment for psoriasis (e.g., infliximab, adalimumab, etanercept, ustekinumab, secukinumab, or alefacept).
7. Have received treatment for any type of cancer within 5 years of the Baseline Visit except skin cancer and cervical cancer (in situ) are allowed if at least 1 year before the Baseline Visit.
8. Use within 60 days prior to the Baseline Visit of: 1) systemic or topical immunosuppressive drugs (e.g., tacrolimus, pimecrolimus), 2) systemic antipsoriatic treatment (e.g., methotrexate, cyclosporine, hydroxyurea) or 3) oral retinoids (e.g., acitretin, isotretinoin).
9. Use within 30 days prior to the Baseline Visit of: 1) systemic steroids, 2) PUVA therapy, 3) systemic anti inflammatory agents (e.g., mycophenolate mofetil, sulfasalazine, 6 thioguanine), or 4) UVB therapy. Inhaled, intraocular, and intranasal steroids are allowed.

10. Use within 14 days prior to the Baseline Visit of: 1) topical antipsoriatic drugs (e.g., salicylic acid, anthralin, coal tar, calcipotriene), 2) topical retinoids (e.g., tazarotene, tretinoin) or 3) topical corticosteroids.
11. Subjects who have participated in a study of an investigational drug 60 days prior to the Baseline Visit.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: DFD-06 Cream DFD-06 Cream will be applied to subjects with moderate plaque psoriasis twice daily for 14 days.	Drug: DFD06 Cream • Twice daily topical application for 14 days. • Other Names: ◦ Clobetasol propionate Cream, 0.025%
Placebo Comparator: Vehicle Cream Vehicle Cream will be applied to subjects with moderate plaque psoriasis twice daily for 14 days.	Drug: Vehicle Cream • Twice daily topical application for 14 days.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Subjects With Treatment Success at Day 15	The percentage of subjects with treatment success (defined as IGA = 0 or 1 and at least a 2-grade reduction from baseline) at the Day 15 visit. Primary analysis was done with multiple imputations. Results are combined analyses from 5 imputed data sets.	Day 15 Visit

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percent Change From Baseline in Body Surface Area at Day 15	Percent change from baseline in body surface area affected by psoriasis at Day 15. The analysis was done with multiple imputations. Results are combined analyses from 5 imputed data sets.	Baseline and Day 15
Percent of Subjects With Treatment Success at Day 8 Visit	Percent of subjects with treatment success at Day 8 Visit defined as an IGA of 0 or 1 with at least a 2 grade reduction from baseline. The analysis was done with multiple imputations. Results are combined analyses from 5 imputed data sets.	Baseline and Day 8

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Promius Pharma, LLC

Collaborators

No information provided

Investigators

- Study Director: Srinivas Sidgiddi, MD, Dr. Reddy s Laboratories, Inc

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

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Study Record Dates

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Study Registration Dates

First Submitted
2015-12-08

First Submitted that Met QC Criteria
2015-12-15

First Posted (Estimated)
2015-12-18

Results Reporting Dates

Results First Submitted
2018-01-31

Results First Submitted that Met QC Criteria
2018-03-15

Results First Posted
2018-04-13

Study Record Updates

Last Update Submitted that met QC Criteria
2018-04-13

Last Update Posted
2018-05-15

Last Verified
2018-04

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Anti Inflammatory Agents
Glucocorticoids
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Physiological Effects of Drugs
Clobetasol

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

Study Documents

No study documents available

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Record 1 of 1

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COMPLETED

Assess the Efficacy and Safety of Alefacept With Narrow Band Ultraviolet B Phototherapy (nbUVB) vs. Alefacept Alone in Chronic Plaque Psoriasis Subjects

ClinicalTrials.gov ID **NCT00658606**

Sponsor Astellas Pharma Inc

Information provided by Astellas Pharma Inc (Responsible Party)

Last Update Posted 2013 01 08

Study Details Tab

Study Overview

Brief Summary

Feedback

Assess the efficacy and safety of alefacept with nbUVB compared to alefacept alone in chronic plaque psoriasis subjects. Combination therapy may improve the clinical response to psoriatic subjects as both modalities have an effect on T cells

Official Title

Efficacy and Safety of Alefacept in Combination With Narrow band UVB (nbUVB) Compared to Alefacept Alone in Subjects With Moderate to Severe Chronic Plaque Psoriasis

Conditions

Plaque Psoriasis

Intervention / Treatment

- Drug: alefacept
- Procedure: Narrow Band UVB Phototherapy

Other Study ID Numbers

- AME 001

Study Start

2007 10

Primary Completion (Actual)

2009 12

Study Completion (Actual)

2009 12

Enrollment (Actual)

98

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Canada

Quebec, Canada, G1J 1X7

Alberta Locations

Calgary, Alberta, Canada, T2S 3B3

British Columbia Locations

Surrey, British Columbia, Canada, V3R 6A7

Vancouver, British Columbia, Canada, V5Z 4E8

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Subject has given written informed consent
- Subject has a diagnosis of moderate to severe chronic plaque psoriasis involving >=10% with a Psoriasis Area and Severity Index (PASI) score >=10 at Baseline
- Subject has CD4+ T lymphocyte (CD4) count at or above the lower limit of normal
- Male and female subjects must use an adequate means of contraception from screening to end of study.

Exclusion Criteria:

- Subject who received alefacept in the past
- Subject who has shown no improvement following an adequate course of nbUVB in the past
- Subject who has been treated in the past with either therapy or cyclosporine
- Subject with any active cancer, including skin cancer at Baseline
- Subject with erythrodermic, pustular or predominantly guttate psoriasis
- Subject who has used treatment for psoriasis prior to Baseline as follows:
    - Topical treatment within 14 days
    - Oral treatment within 28 days
    - Broad band UVB (bbUVB) or nbUVB treatment within 56 days
    - Biological treatment within 84 days
- Serious local infection or serious systemic infection within the 3 months prior to the first dose of study drug
- Subject with a history of drug or alcohol abuse within the past 2 years
- Subject that is known to be infected with the AIDS virus
- Subject with any other skin disease or other disease that might interfere with psoriasis status assessments
- Female subject who is nursing, pregnant or planning to become pregnant while in this study
- Subject who is currently enrolled in any other investigational drug or device study

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment

Active Comparator: Alefacept alone
 	
15 mg alefacept intramuscularly (IM) once weekly for 12 weeks
	Drug: alefacept
	• IM
	• Other Names:
	  ◦ Amevive
	  ◦ ASP0485

Experimental: Alefacept + nbUVB 15 mg alefacept intramuscularly once weekly and narrow band Ultraviolet B (nbUVB) phototherapy 3 times per week for 12 weeks	Procedure: Narrow Band UVB Phototherapy • UVB Phototherapy

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Subjects Who Achieve Psoriasis Area and Severity Index (PASI) 75 at Week 16	The PASI score is a tool that allows investigators to assign an objective number to the degree of severity of a person s psoriasis, and considers: redness, scaling and thickness. Values for PASI score range from 0 (least) to 72 (worst). PASI 75 was defined as an improvement of at least 75% in PASI as compared to Baseline. The Last Observation Carry Forward (LOCF) method was used to impute missing data.	Week 16

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Subjects Reaching PASI 75 Over the Entire Course of the Study	The PASI score is a tool that allows investigators to assign an objective number to the degree of severity of a person s psoriasis, and considers: redness, scaling and thickness. Values for PASI score range from 0 (least) to 72 (worst). PASI 75 was defined as an improvement of at least 75% in PASI as compared to Baseline. The Last Observation Carry Forward (LOCF) method was used to impute missing data.	Week 36
Change in Body Surface Area (BSA) Covered With Psoriasis at Week 16	A negative change from Baseline represents improvement. Change is calculated as Week 16- Baseline.	Baseline and Week 16

	The Last Observation Carry Forward (LOCF) method was used to impute missing data.	
Change in Body Surface Area (BSA) Covered With Psoriasis Over the Entire Course of the Study	A negative change from Baseline represents improvement. Change is calculated as Week 36- Baseline. The Last Observation Carry Forward (LOCF) method was used to impute missing data.	Baseline and Week 36
Percentage of Subjects Who Achieved Physical Global Assessment (PGA) of Clear or Almost Clear at Week 16	The PGA scale is a tool used to evaluate the degree of overall lesion severity. The scale ranges from 0 (clear) to 5 (very severe). Clear is defined as a score of 0; Almost Clear is defined as a score of 1. Subjects who achieved PGA of clear or almost clear at any visit during the study were assigned to the YES category for their respective groups. The Last Observation Carry Forward (LOCF) method was used to impute missing data.	Week 16
Percentage of Subjects Who Achieved Physical Global Assessment (PGA) of Clear or Almost Clear Over the Entire Course of the Study	The PGA scale is a tool used to evaluate the degree of overall lesion severity. The scale ranges from 0 (clear) to 5 (very severe). Clear is defined as a score of 0; Almost Clear is defined as a score of 1. Subjects who achieved PGA of clear or almost clear at any visit during the study were assigned to the YES category for their respective groups. The Last Observation Carry Forward (LOCF) method was used to impute missing data.	Week 36

Percentage of Subjects Who Achieve PASI 90 at Week 16	The PASI score is a tool that allows investigators to assign an objective number to the degree of severity of a person s psoriasis, and considers: redness, scaling and thickness. Values for PASI score range from 0 (least) to 72 (worst). PASI 90 was defined as an improvement of at least 90% in PASI as compared to Baseline. The Last Observation Carry Forward (LOCF) method was used to impute missing data.	Week 16
Time to Relapse	The analysis only included subjects who achieved a 75% improvement in PASI and then relapsed. Relapse is defined by a loss of 50% of improvement in PASI.	Week 36
Time for 50% Decrease in PASI	The PASI score is a tool that allows investigators to assign an objective number to the degree of severity of a person s psoriasis, and considers: redness, scaling and thickness. Values for PASI score range from 0 (least) to 72 (worst). Only subjects who experienced 50% decrease in PASI were included in the analysis.	Week 36
Time for a 75% Decrease in PASI	The PASI score is a tool that allows investigators to assign an objective number to the degree of severity of a person s psoriasis, and considers: redness, scaling and thickness. Values for PASI score range from 0 (least) to 72 (worst).	Week 36

	Only subjects who experienced 75% decrease in PASI were included in the analysis.	
Change in Dermatology Life Quality Index (DLQI)	The DLQI questionnaire is intended to measure how much a subject s skin problem affects the subject s life. Subjects provide answers considering the past week. The scale of the DQLI ranges from 0 (best) to 30 (worst). A negative change from Baseline represents improvement. Change is calculated as Week 36- Baseline. The Last Observation Carry Forward (LOCF) method was used to impute missing data.	Baseline and Week 36

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Astellas Pharma Inc

Collaborators

- Astellas Pharma Canada, Inc.

Investigators

- Study Director: Use Central Contact, Astellas Pharma Canada, Inc.

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

- Lui H, Gulliver W, Tan J, Hong CH, Hull P, Shear NH, Paradiso Hardy F, Bissonette R. A randomized controlled study of combination therapy with alefacept and narrow band UVB phototherapy (UVB) for moderate to severe psoriasis: efficacy, onset, and duration of response. J Drugs Dermatol. 2012 Aug;11(8):929 37. (https://pubmed.ncbi.nlm.nih.gov/22859237)

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2008-04-10

First Submitted that Met QC Criteria
2008-04-10

First Posted (Estimated)
2008-04-15

Results Reporting Dates

Results First Submitted
2011-02-17

Results First Submitted that Met QC Criteria
2011-03-28

Results First Posted (Estimated)
2011-04-22

Study Record Updates

Last Update Submitted that met QC Criteria
2013-01-03

Last Update Posted (Estimated)

2013-01-08

Last Verified

2013-01

More Information

Terms related to this study

Keywords Provided by Astellas Pharma Inc

plaque psoriasis
alefacept
Amevive
narrow band ultraviolet B
phototherapy

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Dermatologic Agents
Immunologic Factors
Physiological Effects of Drugs
Alefacept

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by Astellas Pharma Inc

Link to Prescribing Information (http://www.astellas.us/docs/amevive.pdf)

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full disclaimer (https://clinicaltrials.gov/about site/disclaimer) for details.

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Observational Safety Study of Etanercept (Enbrel) for Treatment of Psoriasis

ClinicalTrials.gov ID NCT00322439

Sponsor Amgen

Information provided by Amgen (Responsible Party)

Last Update Posted 2018 06 28

Study Details Tab

Study Overview

Brief Summary

This is an observational safety study tracking psoriasis patients on etanercept (Enbrel) for 5 years.

Detailed Description

Feedback

This is a prospective, multi center, observational surveillance registry to evaluate data on the long term safety of etanercept (Enbrel) use in the treatment of psoriasis.

Official Title

Observational Post Marketing Safety Surveillance Registry of Enbrel (Etanercept) for Treatment of Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Etanercept

Other Study ID Numbers

- 20040210

Study Start (Actual)

2006 05 01

Primary Completion (Actual)

2012 12 11

Study Completion (Actual)

2013 02 08

Enrollment (Actual)

2511

Study Type

Observational [Patient Registry]

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Etanercept (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Etanercept)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

No location data

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person s general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Patients with plaque psoriasis

Exclusion Criteria:

- Prior exposure to any tumor necrosis factor (TNF) inhibitor
- Patients for whom Enbrel is contraindicated
- Patients currently enrolled in or has not yet completed at least 30 days since ending other investigational drug study.

Study Population

Patients with plaque psoriasis, who are currently receiving Enbrel or who are intending to start or restart Enbrel therapy at multi centers.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Sampling Method

Probability Sample

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Observational Model : Cohort
Time Perspective: Prospective
Target Follow-up Duration: 5 Years
Biospecimen Retention: Samples With DNA
Biospecimen Description: Whole blood, serum, plasma.

Cohorts and Interventions

Group/Cohort	Intervention/Treatment
Etanercept Participants received etanercept (Enbrel) treatment at the dose and regimen determined by the investigator and were evaluated for up to 5 years at 6-month intervals. During this period, participants may have discontinued etanercept therapy, may have switched to another anti-psoriatic therapy, may have used etanercept in combination with other anti-psoriatic therapies, or may have discontinued any or all antipsoriatic treatments.	Drug: Etanercept • Observational study - no drug administered

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Five-year Cumulative Incidence of Serious Adverse Events and Serious Infectious Events	A serious adverse event (SAE), including a serious infectious event (SIE), is defined as one that suggests a significant hazard or side effect, regardless of the investigator or sponsor s opinion on the relationship to a drug product. This includes, but may not be limited to, any event that (at any dose) is fatal, life threatening, requires inpatient hospitalization that includes a minimum of an overnight stay or prolongation of existing hospitalization, is a persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. Cumulative incidences were calculated using Kaplan-Meier methodology for all participants who received at least 1 registry dose of etanercept. For SAEs and SIEs, time to event was re-defined from calendar time to cumulative time up to the event, excluding time intervals and events when the participant was not on etanercept treatment (ie, based on etenercept exposure time).	5 years

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Five-year Cumulative Incidence for Events of Medical Interest (EMIs)	Protocol defined EMIs included: • All malignancies, including basal cell carcinoma (BCC) and squamous cell carcinoma (SCC); • Tuberculosis; • Opportunistic infections treated with intravenous therapy; • Histoplasmosis infections treated with oral antibiotics; • Coccidioidomycosis infections treated with oral antibiotics; • Central nervous system (CNS) demyelinating disorders; • Lupus disease; • Coronary artery disease; • Worsening of	5 years

	psoriasis as defined by change in psoriasis morphology and withdrawal of therapy; • Any event or laboratory abnormality that represents an event of medical significance. Cumulative incidences were calculated using Kaplan-Meier methods where time to event was defined as the time from the first dose of etanercept to the start date of the first occurrence of the event, regardless of exposure (ie, based on observation time). Estimates were adjusted using left truncation methodology to help address any bias due to participants with prior etanercept exposure.	
Percentage of Participants With a Static Physician s Global Assessment (sPGA) of Psoriasis Score of 0 (Clear) or 1 (Almost Clear)	The sPGA scale is designed to evaluate the physician s global assessment of the participant s psoriasis based on severity of induration, scaling, and erythema. The sPGA is assessed on a scale of 0 to 5 (0 = clear, 5 = severe).	Baseline and at 3 and 5 years
Percentage of Participants With a Patient s Global Assessment of Psoriasis Score of 0 or 1	The patient s global assessment of psoriasis is a self-administered numeric scale is designed to evaluate participants perception of their psoriasis on a scale from 0 (good) to 5 (severe).	Baseline and at 3 and 5 years

Percentage of Participants With a Dermatology Life Quality Index (DLQI) Response	The DLQI questionnaire asks participants to evaluate the degree that psoriasis has affected their quality of life in the last week, and includes the following parameters: symptoms and feelings, daily activities, leisure activities, work or school activities, personal relationships and treatment related feelings. Participants answer 10 questions on a scale from 0 (not at all) to 3 (very much); the range of the total score is 0 to 30. A score of 21 to 30 means an extremely large effect on the participant s life whereas 0-1 means that the disease has no effect at all. A DLQI response is defined as a 5 point improvement from Baseline or a score of 0.	Baseline, Year 3 and Year 5
Euroqol-5D (EQ-5D) Total Score	EQ-5D is a self-reported questionnaire that consists of five single-item health domains, mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The answers are recorded as choices of 1, 2, or 3 for each question, with 1 signifying no problem, 2 signifying some problem, and 3 signifying major problem. Using the US scoring algorithm, the possible total EQ-5D score ranges from -0.11 (ie, answered 3 for all questions) to 1.0 (ie, answered 1 for all questions), where 1.0 represents perfect health.	Baseline, Year 3 and Year 5
Euroqol-5D (EQ-5D) Visual Analog Scale (VAS)	The EQ-5D visual analog scale (VAS) is a 100 mm scale with 100 representing best imaginable health state and 0 representing worst imaginable health state . Participants were asked to indicate on this scale how good or bad their health was today.	Baseline, Year 3 and Year 5
Healthcare Resource Use	This self-administered questionnaire is designed to measure the amount of healthcare resource utilization by the participant in the past 4 weeks.	Baseline, Year 3 and Year 5

	The average answers to the following questions are reported: 1. How many times have you been to any physician s office or urgent care clinic, not including your dermatologist? 2. How many times have you seen a nurse practitioner, physician assistant, psychologist, naturopath, acupuncturist, or chiropractor? 3. How many times have you received care from a health professional (HP) in your home? 4. How many times have you paid someone to help you do chores around the house (cleaning, maintenance, lawn care)? 5. How many times have you had a friend or family member take time off work to provide care or transportation?	
Work Productivity and Activity Impairment (WPAI)	The WPAI questionnaire has six questions to assess whether the participant was currently employed (Q1); how many hours from work were missed due to problems associated with psoriasis (Q2) or any other reason (Q3); hours actually worked (Q4); degree that psoriasis affected productivity while working (Q5); and degree that psoriasis affected regular activities (Q6) over the past 7 days. Four separate overall scores were calculated, including absenteeism (work time missed due to health), presenteeism (impairment at work due to health), work productivity loss (overall work impairment due to health), and activity impairment due to health. Each score ranges from 0 to 100 with higher scores indicating greater impairment and less productivity (ie, worse outcomes).	Baseline, Year 3 and Year 5
Percentage of Body Surface	Body Surface Area (BSA) is a numerical score used to measure the physician s assessment of	Baseline, Year 3

Area Affected by Psoriasis	the percentage of the participant s total BSA involved with psoriasis.	and Year 5

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Amgen

Collaborators

No information provided

Investigators

- Study Director: MD, Amgen

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

- Kimball AB, Pariser D, Yamauchi PS, Menter A, Teller CF, Shi Y, Creamer K, McCroskery P, Kricorian G, Gelfand JM. OBSERVE 5, an Observational Post Marketing SafetySurveillance Registry of Etanercept for the treatment of Psoriasis: A Model for Studying New Psoriasis Therapies. Psoriasis Forum. 2010;16(3):3 7.
- Kimball AB, Pariser D, Yamauchi PS, Menter A, Teller CF, Shi Y, Yong M, Creamer K, Hooper M, Aras G, Kricorian G, Gelfand JM. OBSERVE 5 interim analysis: an observational postmarketing safety registry of etanercept for the treatment of psoriasis. J Am Acad Dermatol. 2013 May;68(5):756 64. doi: 10.1016/j.jaad.2012.10.055. Epub 2013 Jan 26. (https://pubmed.ncbi.nlm.nih.gov/23357569)
- Kimball AB, Rothman KJ, Kricorian G, Pariser D, Yamauchi PS, Menter A, Teller CF, Aras G, Accortt NA, Hooper M, Rice KC, Gelfand JM. OBSERVE 5: observational postmarketing safety surveillance registry of etanercept for the treatment of psoriasis final 5 year results. J Am Acad Dermatol. 2015 Jan;72(1):115 22. doi: 10.1016/j.jaad.2014.08.050. Epub 2014 Sep 26. (https://pubmed.ncbi.nlm.nih.gov/25264239)

- Kimball AB, Schenfeld J, Accortt NA, Anthony MS, Rothman KJ, Pariser D. Incidence rates of malignancies and hospitalized infectious events in patients with psoriasis with or without treatment and a general population in the U.S.A.: 2005 09. Br J Dermatol. 2014 Feb;170(2):366 73. doi: 10.1111/bjd.12744. (https://pubmed.ncbi.nlm.nih.gov/24251402)

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2006-05-05

First Submitted that Met QC Criteria
2006-05-05

First Posted (Estimated)
2006-05-08

Results Reporting Dates

Results First Submitted
2014-02-11

Results First Submitted that Met QC Criteria
2014-02-11

Results First Posted (Estimated)
2014-03-26

Study Record Updates

Last Update Submitted that met QC Criteria
2018-05-09

Last Update Posted

2018-06-28

Last Verified

2018-05

More Information

Terms related to this study

Keywords Provided by Amgen

plaque Psoriasis patients
TNF inhibitor naïve

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Anti Inflammatory Agents, Non Steroidal
Analgesics, Non Narcotic
Analgesics
Sensory System Agents
Peripheral Nervous System Agents
Physiological Effects of Drugs
Anti Inflammatory Agents
Antirheumatic Agents
Gastrointestinal Agents
Immunosuppressive Agents
Immunologic Factors
Etanercept

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by Amgen

AmgenTrials clinical trials website (http://www.amgentrials.com)

Record 1 of 1

The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full disclaimer (https://clinicaltrials.gov/about site/disclaimer) for details.

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

A Study to Evaluate the Safety and Efficacy of Adalimumab in Subjects With Chronic Plaque Psoriasis and Nail Psoriasis

ClinicalTrials.gov ID **NCT02016482**

Sponsor AbbVie

Information provided by AbbVie (Responsible Party)

Last Update Posted 2017 05 30

Study Details Tab

Study Overview

Brief Summary

This study is being conducted to assess the safety and efficacy of adalimumab in participants with nail psoriasis.

Feedback

Official Title

A Phase 3, Multicenter, Double Blind, Randomized, Parallel Arm, Placebo Controlled Study to Evaluate the Safety and Efficacy of Adalimumab for Treatment of Nail Psoriasis in Patients With Chronic Plaque Psoriasis

Conditions

Nail Psoriasis Plaque Psoriasis

Intervention / Treatment

- Biological: Adalimumab
- Other: Placebo

Other Study ID Numbers

- M13 674
- 2013 003275 36 (EudraCT Number)

Study Start

2014 01

Primary Completion (Actual)

2015 10

Study Completion (Actual)

2016 04

Enrollment (Actual)

217

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Adalimumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Adalimumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

No location data

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person s general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Subject must have body surface area (BSA) ≥ 10% and a target fingernail Modified Nail Psoriasis Severity Index (mNAPSI) ≥ 8 at Week 0, OR BSA ≥ 5%, a target fingernail mNAPSI ≥ 8 and a total mNAPSI score of ≥ 20 at Week 0.
- Subject must have a Nail Psoriasis Physical Functioning Severity score of > 3, OR a Nail Psoriasis Pain Numeric Rating Scale (NRS) score of >3.
- Subjects must have a Physicians Global Assessment (PGA) of Fingernail Psoriasis and a PGA of Skin Psoriasis of at least moderate.
- Subject must have discontinued use of all systemic therapies for the treatment of psoriasis, or systemic therapies known to improve psoriasis for at least 4 weeks prior to Week 0, ustekinumab must have been discontinued at least 12 weeks prior to Week 0.
- Target fingernail must have mNAPSI score of ≥ 8.
- Adult subjects with clinical diagnosis of chronic plaque psoriasis (with disease duration of at least 6 months).

Exclusion Criteria:

- Prior adalimumab therapy.
- Diagnosis of other active skin diseases or skin infections (bacterial, fungal, or viral) that may interfere with evaluation of skin or fingernail psoriasis.
- Recent infection requiring treatment.
- Significant medical events or conditions that may put patients at risk for participation, including recent history of drug or alcohol abuse.
- Female subjects who are pregnant or breast feeding or considering becoming pregnant during the study.
- History of cancer, except successfully treated skin cancer.

Ages Eligible for Study

18 Years to 99 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Active Comparator: Adalimumab (ADA) Period A: ADA 40 mg subcutaneous every other week (sc eow) for 25 weeks starting 1 week after initial loading dose of 80 mg. Period B: Placebo at Week 26 followed by ADA 40 mg sc eow from Week 27 through Week 51.	Biological: Adalimumab • Other Names: ◦ ABT-D2E7 ◦ Humira Other: Placebo
Placebo Comparator: Placebo Period A: Placebo sc eow for 25 weeks. Period B: ADA 80 mg sc at Week 26 followed by ADA 40 mg sc eow from Week 27 through Week 51.	Biological: Adalimumab • Other Names: ◦ ABT-D2E7 ◦ Humira Other: Placebo

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants	Each fingernail was assessed for psoriasis with mNAPSI, and the scores of all 10 fingernails were	Week 26

Achieving a Total Fingernail Modified Nail Psoriasis Severity Index (mNAPSI) 75 Response at Week 26	combined. Investigators assessed each nail abnormality for each of a participant s nails by grading 3 features or groups of features (pitting, onycholysis and oil-drop dyschromia, and crumbling) and noting the presence or absence of 4 features (leukonychia, splinter hemorrhages, hyperkeratosis, and red spots in the lunula). The range of possible scores was 0 to 130, with a score of 0 indicating absence of nail psoriasis and a score of 130 indicating the most severe nail psoriasis. A decrease in mNAPSI score indicates improvement. The mNAPSI 75 response is defined as at least 75% reduction from baseline in mNAPSI.	
For United States (US) Regulatory Purposes: Percentage of Participants With a Physician s Global Assessment of Fingernails (PGA-F) of "Clear" or "Minimal" at Week 26	The PGA-F is a 5-point scale used to assess fingernails separately for nail bed signs and nail matrix signs of disease. A global score of between 0 indicating clear, and 4 indicating severe, was separately assigned for nail bed involvement and nail matrix involvement. A participant s overall global score was the worse of the nail bed and nail matrix score. Data presents the percentage of participants with a PGA-F overall global score that met the definition of "clear" (0) or "minimal" (1) with at least a 2-grade improvement relative to Baseline at Week 26.	Week 26

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percent Change From Baseline in Total Fingernail Nail Psoriasis	Each fingernail was assessed for nail matrix psoriasis and nail bed psoriasis with NAPSI and the scores of all 10 fingernails were combined. The range of possible scores was 0 to 80, with a score of 0 indicating absence of nail psoriasis	Baseline, Week 26

Severity Index (NAPSI) Score at Week 26	and 80 indicating most severe nail psoriasis. A decrease in NAPSI score indicates improvement.	
Percentage of Participants Achieving Total Fingernail mNAPSI Score of 0 at Week 26	Each fingernail was assessed for psoriasis with mNAPSI, and the scores of all 10 fingernails were combined. The range of possible scores was 0 to 130, with a score of 0 indicating absence of nail psoriasis and a score of 130 indicating the most severe nail psoriasis. A decrease in mNAPSI score indicates improvement.	Week 26
Percent Change From Baseline in Nail Psoriasis Pain Numeric Rating Scale (NRS) at Week 26	An NRS was used to capture a participant s self-reporting of her/his worst fingernail pain and average fingernail pain due to fingernail psoriasis. The participant rated the severity of fingernail pain over the past 7 days on a scale from 0 indicating no pain, to 10 indicating severe pain. A negative change from Baseline indicates improvement.	Baseline, Week 26
Change From Baseline in Nail Psoriasis Physical Functioning Severity Score at Week 26	Participants were asked to rate the impact of their fingernail psoriasis on their ability to perform physical tasks (eg, typing, housework, buttoning a shirt or blouse, picking up coins from a table, tying shoes, yard work, etc.) over the past 7 days on a scale of 0 indicating no impact on ability to perform physical tasks, to 10 indicating severe impact on ability to perform physical tasks. A negative change from Baseline indicates improvement.	Baseline, Week 26
Percentage of Participants With at Least 50% Improvement in the Scalp Component of	The range of possible scores was 0 to 20 for scalp psoriasis, with a score of 0 indicating absence of psoriasis. A decrease in B-SNIPI score indicates improvement. Data presents the percentage of participants achieving 50% improvement in the scalp component of the B-	Baseline, Week 26

the Brigham Scalp Nail Inverse Palmo-Plantar Psoriasis Index (B-SNIPI) at Week 26	SNIPI among participants with Baseline scalp score of ≥ 6.	
Percentage of Participants Achieving "Clear" or "Minimal" in Nail Bed Component of the PGA-F at Week 26	The PGA-F is a 5-point scale used to assess fingernails separately for nail bed signs and nail matrix signs of disease. A global score of between 0 indicating clear, and 4 indicating severe, was separately assigned for nail bed involvement and nail matrix involvement. A participant s overall global score was the worse of the nail bed and nail matrix score. Data presents the percentage of participants with a nail bed component of the PGA-F that met definition of "clear" (0) or "minimal" (1) among those with a Baseline nail bed component of "moderate" or "worse."	Week 26
Percentage of Participants Achieving "Clear" or "Minimal" in Nail Matrix Component of the PGA-F At Week 26	The PGA-F is a 5-point scale used to assess fingernails separately for nail bed signs and nail matrix signs of disease. A global score of between 0 indicating clear, and 4 indicating severe, was separately assigned for nail bed involvement and nail matrix involvement. A participant s overall global score was the worse of the nail bed and nail matrix score. Data presents the percentage of participants with a nail matrix component of the PGA-F that met definition of "clear" (0) or "minimal" (1) among those with a Baseline nail matrix component of "moderate" or "worse."	Week 26
Percentage of Participants Achieving Target	The target fingernail was assessed for psoriasis with mNAPSI. The range of possible scores was 0 to 13, with a score of 0 indicating absence of nail psoriasis and a score of 13 indicating the	Week 26

Fingernail mNAPSI Score of 0 at Week 26	most severe nail psoriasis. A decrease in mNAPSI score indicates improvement.	
Percentage of Participants Achieving Target Fingernail mNAPSI Score of ≤ 2 at Week 26	The target fingernail was assessed for psoriasis with mNAPSI. The range of possible scores was 0 to 13, with a score of 0 indicating absence of nail psoriasis and a score of 13 indicating the most severe nail psoriasis. A decrease in mNAPSI score indicates improvement.	Week 26
Percentage of Participants Achieving Total Fingernail mNAPSI Score of ≤ 2 at Week 26	Each fingernail was assessed for psoriasis with mNAPSI, and the scores of all 10 fingernails were combined. The range of possible scores was 0 to 130, with a score of 0 indicating absence of nail psoriasis and a score of 130 indicating the most severe nail psoriasis. A decrease in mNAPSI score indicates improvement.	Week 26
Change From Baseline in Target Fingernail mNAPSI Score at Week 26	The target fingernail was assessed for psoriasis with mNAPSI. The range of possible scores was 0 to 13, with a score of 0 indicating absence of nail psoriasis and a score of 13 indicating the most severe nail psoriasis. A decrease in mNAPSI score indicates improvement.	Baseline, Week 26
Percent Change From Baseline in Target Fingernail mNAPSI Score at Week 26	The target fingernail was assessed for psoriasis with mNAPSI. The range of possible scores was 0 to 13, with a score of 0 indicating absence of nail psoriasis and a score of 13 indicating the most severe nail psoriasis. A decrease in mNAPSI score indicates improvement.	Baseline, Week 26
Change From Baseline in Total Fingernail	Each fingernail was assessed for psoriasis with mNAPSI, and the scores of all 10 fingernails were combined. The range of possible scores was 0 to 130, with a score of 0 indicating	Baseline, Week 26

mNAPSI Score at Week 26	absence of nail psoriasis and a score of 130 indicating the most severe nail psoriasis. A decrease in mNAPSI score indicates improvement.	
Percent Change From Baseline in Total Fingernail mNAPSI Score at Week 26	Each fingernail was assessed for psoriasis with mNAPSI, and the scores of all 10 fingernails were combined. The range of possible scores was 0 to 130, with a score of 0 indicating absence of nail psoriasis and a score of 130 indicating the most severe nail psoriasis. A decrease in mNAPSI score indicates improvement.	Baseline, Week 26
Percentage of Participants Achieving Total Fingernail NAPSI Score of 0 at Week 26	Each fingernail was assessed for nail matrix psoriasis and nail bed psoriasis with NAPSI and the scores of all 10 fingernails were combined. The range of possible scores was 0 to 80, with a score of 0 indicating absence of nail psoriasis and 80 indicating most severe nail psoriasis. A decrease in NAPSI score indicates improvement.	Week 26
Percentage of Participants Achieving Target Fingernail NAPSI Score of 0 at Week 26	The target fingernail was assessed for nail matrix psoriasis and nail bed psoriasis with NAPSI. The range of possible scores was 0 to 8, with a score of 0 indicating absence of nail psoriasis and 8 indicating most severe nail psoriasis. A decrease in NAPSI score indicates improvement.	Week 26
Change From Baseline in Target Fingernail NAPSI Score at Week 26	The target fingernail was assessed for nail matrix psoriasis and nail bed psoriasis with NAPSI. The range of possible scores was 0 to 8, with a score of 0 indicating absence of nail psoriasis and 8 indicating most severe nail psoriasis. A decrease in NAPSI score indicates improvement.	Baseline, Week 26

Percent Change From Baseline in Target Fingernail NAPSI Score at Week 26	The target fingernail was assessed for nail matrix psoriasis and nail bed psoriasis with NAPSI. The range of possible scores was 0 to 8, with a score of 0 indicating absence of nail psoriasis and 8 indicating most severe nail psoriasis. A decrease in NAPSI score indicates improvement.	Baseline, Week 26
Change From Baseline in Total Fingernail NAPSI Score at Week 26	Each fingernail was assessed for nail matrix psoriasis and nail bed psoriasis with NAPSI and the scores of all 10 fingernails were combined. The range of possible scores was 0 to 80, with a score of 0 indicating absence of nail psoriasis and 80 indicating most severe nail psoriasis. A decrease in NAPSI score indicates improvement.	Baseline, Week 26
Change From Baseline in Psoriasis Area Severity Index (PASI) Score at Week 26	PASI is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (plaque thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The score ranges from 0 to 72, with 0 indicating no psoriasis and 72 indicating very severe psoriasis. A decrease in PASI score indicates improvement.	Baseline, Week 26
Percent Change From Baseline in PASI Score at Week 26	PASI is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (plaque thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The score ranges from 0 to 72, with 0 indicating no psoriasis and 72 indicating very severe psoriasis. A decrease in PASI score indicates improvement.	Baseline, Week 26

Percentage of Participants Achieving PASI 75/50/90/100 Responses at Week 26	PASI is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (plaque thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The score ranges from 0 to 72, with 0 indicating no psoriasis and 72 indicating very severe psoriasis. PASI-75, 50, 90, and 100 responses are the percentage of participants with a Baseline PASI score ≥ 5 who achieved at least a 75%, 50%, 90%, or 100% reduction (improvement), respectively, from Baseline in PASI score at Week 26. A 100% reduction was considered complete clearance of psoriasis. Data presents the percentage of participants achieving PASI 75/50/90/100 responses at Week 26 among participants with a Baseline PASI score ≥ 5.	Week 26
Percentage of Participants Achieving Physician s Global Assessment of Skin Psoriasis (PGA-S) "Clear" or "Minimal" at Week 26	The PGA-S is a 6-point scale used to measure the severity of skin disease at the time of the qualified investigator s evaluation of the participant. The degree of overall lesion severity was assessed, with 0 indicating cleared and 5 indicating severe. A decrease in PGA-S score indicates improvement. Data present the percentage of participants achieving a PGA-S of "clear" (0) or "minimal" (1) with at least a 2-grade improvement relative to Baseline at Week 26.	Week 26
Percentage of Participants Achieving PGA-S of "Clear" at Week 26	The PGA-S is a 6-point scale used to measure the severity of skin disease at the time of the qualified investigator s evaluation of the participant. The degree of overall lesion severity was assessed, with 0 indicating cleared and 5 indicating severe. A decrease in PGA-S score indicates improvement. Data present the percentage of participants achieving a PGA-S of	Week 26

	"clear" (0) with at least a 2-grade improvement relative to Baseline at Week 26.	
Percentage of Participants Achieving 50% Improvement in the Inverse Psoriasis Component of the B-SNIPI at Week 26	The range of possible B-SNIPI scores was 0 to 20 for inverse psoriasis, with a score of 0 indicating absence of psoriasis and a score of 20 indicating most severe psoriasis. A decrease in B-SNIPI score indicates improvement. Data presents the percentage of participants achieving 50% improvement in the inverse component of the B-SNIPI among participants with a Baseline inverse psoriasis score of ≥ 6.	Week 26
Change From Baseline in Total Body Surface Area (BSA) at Week 26	BSA affected by psoriasis was measured by the physician selecting the participant s right or left hand as the measuring device. For purposes of clinical estimation, the total surface of the palm plus 5 digits was to be assumed to be approximately equivalent to 1% BSA. Measurement of the total area of involvement by the physician was aided by imagining if scattered plaques were moved so that they were next to each other and then estimated the total area involved. A decrease in BSA affected by psoriasis indicates improvement.	Baseline, Week 26
Percent Change From Baseline in Total BSA at Week 26	BSA affected by psoriasis was measured by the physician selecting the participant s right or left hand as the measuring device. For purposes of clinical estimation, the total surface of the palm plus 5 digits was to be assumed to be approximately equivalent to 1% BSA. Measurement of the total area of involvement by the physician was aided by imagining if scattered plaques were moved so that they were next to each other and then estimated the total area involved. A decrease in BSA affected by psoriasis indicates improvement.	Baseline, Week 26

Percent Change From Baseline in Nail Psoriasis Pain NRS at Week 26	An NRS was used to capture a participant s self-reporting of her/his worst fingernail pain and average fingernail pain due to fingernail psoriasis. The participant rated the severity of fingernail pain over the past 7 days on a scale from 0 indicating no pain, to 10 indicating severe pain. A negative change from Baseline indicates improvement.	Baseline, Week 26
Percent Change From Baseline in Nail Psoriasis Physical Functioning Severity Score at Week 26	Participants were asked to rate the impact of their fingernail psoriasis on their ability to perform physical tasks (eg, typing, housework, buttoning a shirt or blouse, picking up coins from a table, tying shoes, yard work, etc.) over the past 7 days on a scale of 0 indicating no impact on ability to perform physical tasks, to 10 indicating severe impact on ability to perform physical tasks. A negative change from Baseline indicates improvement.	Baseline, Week 26
Change From Baseline in Nail Assessment in Psoriasis and Psoriatic Arthritis Quality of Life (NAPPA QoL) at Week 26	Participants rated specific impacts of fingernail psoriasis on various aspects of their QoL over the past 7 days on a 5-point scale, with 0 indicating not at all, and 4 indicating very impactful. A participant s overall global score was the mean of all items and could range from 0 to 4, with 0 indicating no impact and 4 indicating most impact. A decrease in NAPPA QoL score indicates improvement.	Baseline, Week 26
Percent Change From Baseline in Nail Assessment in NAPPA QoL at Week 26	Participants rated specific impacts of fingernail psoriasis on various aspects of their QoL over the past 7 days on a 5-point scale, with 0 indicating not at all, and 4 indicating very impactful. A participant s overall global score was the mean of all items and could range from 0 to 4, with 0 indicating no impact and 4 indicating most impact. A decrease in NAPPA QoL score indicates improvement.	Baseline, Week 26

Change From Baseline in Dermatology Life Quality Index (DLQI) Score at Week 26	Participants assessed symptoms and impacts of dermatologic diseases on their QoL over the past 7 days, with 0 indicating not at all, and 3 indicating very much. The range of possible DLQI scores was 0 to 30, with a score of 0 indicating no effect at all on a participant s life and a score of 30 indicating extremely large effect on participant s life. A decrease in DLQI score indicates improvement.	Baseline, Week 26
Percentage of Participants Achieving DLQI of 0 and 0/1 at Week 26	Participants assessed symptoms and impacts of dermatologic diseases on their QoL over the past 7 days, with 0 indicating not at all, and 3 indicating very much. The range of possible DLQI scores was 0 to 30, with a score of 0 indicating no effect at all on a participant s life and a score of 30 indicating extremely large effect on participant s life. A decrease in DLQI score indicates improvement. Data presents the percentage of participants with a score of 0 (no effect) or 1 (little effect) at Week 26.	Week 26
Change From Baseline in Work Productivity and Activity Impairment Nail Psoriasis (WPAI:NPSO) at Week 26	The WPAI: NPSO assessed impact of fingernail psoriasis on work productivity and non-work activity limitation. Participants were asked during the past 7 days, how many hours did you miss from work because of problems associated with your fingernail psoriasis (absenteeism), during the past seven days, how many hours did you miss from work because of any other reason, such as vacation, holidays, time off to participate in this study (presenteeism), how much did your fingernail psoriasis affect your productivity while you were working (overall work impairment), and much did your fingernail psoriasis affect your ability to do your regular daily activities, other than work at a job (activity impairment). Answers were rated on an 11-point scale, with 0 indicating "fingernail psoriasis had no effect on this" and 10 indicating "fingernail	Baseline, Week 26

	psoriasis completely prevented me from this." A decrease in the WPAI:NPSO score indicates improvement.	
Change From Baseline in EuroQol-5 Dimensions-5 Levels (EQ-5D-5L) Health State Assessment at Week 26	The EQ-5D-5L descriptive system comprises 5 dimensions of health (mobility, self -care, usual activities, pain/discomfort, and anxiety/depression) to describe the subject s current health state. Each dimension comprises 5 levels with corresponding numeric scores, where 1 indicates no problems, and 5 indicates extreme problems. A unique EQ-5D-5L health state is defined by combining the numeric level scores for each of the 5 dimensions and the total score is normalized from -0.594 to 1.000, with higher scores representing a better health state. An increase in the EQ-5D-5L total score indicates improvement.	Baseline, Week 26
Change From Baseline in EQ-5D Visual Analogue Scale (VAS) at Week 26	The EQ-5D VAS records the participant s self-rated health status on a vertical graduated scale from 0 to 100, with 0 indicating the worst imaginable health state and 100 indicating the best imaginable health state. An increase in EQ-5D-5L VAS score indicates improvement.	Baseline, Week 26
Change From Baseline in Hospital Anxiety Depression Scale (HADS) at Week 26	Participants rated their anxiety and depression over the past 7 days at Week 26. The range of possible scores was 0 to 21, with a score of 0 indicating absence of anxiety and depression and 21 indicating the most severe anxiety and depression. A decrease in HADS score indicates improvement.	Baseline, Week 26
Percentage of Participants With a New Diagnosis of Psoriatic	The percentage of participants with a new diagnosis of PsA (ie, with an adverse event of PsA) during the study, among participants without PsA at Baseline.	up to Week 26

Arthritis (PsA) During the Study		
Change From Baseline in Nail Psoriasis Quality of Life (Nail PsQoL) Score at Week 26	Participants were asked how their fingernail psoriasis impacted their overall quality of life over the past 7 days on an 11-point scale, with 0 indicating no impact, and 10 indicating severe impact. A negative change from Baseline indicates improvement.	Baseline, Week 26

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

AbbVie

Collaborators

No information provided

Investigators

- Study Director: David Williams, MD, AbbVie

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2013-12-16

First Submitted that Met QC Criteria
2013-12-16

First Posted (Estimated)
2013-12-20

Results Reporting Dates

Results First Submitted
2016-10-21

Results First Submitted that Met QC Criteria
2016-12-21

Results First Posted
2017-02-13

Study Record Updates

Last Update Submitted that met QC Criteria
2017-04-25

Last Update Posted
2017-05-30

Last Verified
2017-04

More Information

Terms related to this study

Keywords Provided by AbbVie

Nail Psoriasis
Plaque Psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Tumor Necrosis Factor Inhibitors
Anti Inflammatory Agents
Antirheumatic Agents
Adalimumab

Study Documents

No study documents available

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ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

A Study Comparing AIN457 to Placebo in Subjects With a Diagnosis of Moderate to Severe Stable Plaque Psoriasis

ClinicalTrials.gov ID **NCT00669916**

Sponsor Novartis Pharmaceuticals

Information provided by Novartis (Novartis Pharmaceuticals) (Responsible Party)

Last Update Posted 2015 04 10

Study Details Tab

Study Overview

Brief Summary

Feedback

This is a two arm, parallel group, double blind, placebo controlled proof of concept study comparing 3 mg/kg of AIN457 to placebo. Subjects with a diagnosis of moderate to severe stable plaque psoriasis will be randomized to receive either AIN457 or placebo. AIN457 or placebo will be administered by single infusion at baseline and subjects will be observed for up to 26 weeks following the infusion.

Official Title

Phase 2a Single Dose, Randomized, Double Blind, Multi Center, Para lel Group, Placebo Controlled Proof of Concept Study to Assess the Efficacy, Safety, Tolerability, and Population Pharmacokinetics of AIN457 in Patients With Stable Plaque type Psoriasis

Conditions

Plaque Psoriasis

Intervention / Treatment

- Biological: AIN457
- Drug: Placebo

Other Study ID Numbers

- CAIN457A2102

Study Start

2007 02

Primary Completion (Actual)

2007 11

Study Completion (Actual)

2007 11

Enrollment (Actual)

36

Study Type

Interventional

Phase

Phase 1
Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

No location data

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person s general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Males or females, aged 18 69 at time of consent.
- Post menopausal or surgically sterile female patients are allowed. Male patients must be willing to use contraception method at least for 3 months following the completion of the study. Women of child bearing potential will not be allowed to participate.
- Diagnosis of plaque psoriasis for at least 6 months prior to screening. The patients must meet both of the following criterion:
    1. Coverage of the body surface area (BSA) of 10% or more with plaques
    2. A score of 3 or more on the IGA scale
- Stable plaque psoriasis at screening and randomization.
- PASI score of 12 or greater at randomization.
- Able to communicate well with the investigator, and to understand and comply with the requirements of the study. Understand and sign the written informed consent.
- Patients must have normal laboratory values for screening laboratory test results of hematological (hemoglobin, WBCs, neutrophils, platelets) and renal (serum creatinine) assessments. For the transaminases, aspartate aminotransferase and alanine aminotransferase, levels 1.5 times the upper limit of normal will be accepted. For the additional hepatic laboratory results (alkaline phosphatase, gamma glutamyltransferase, bilirubin), patients must have non clinically significant values.

Exclusion Criteria:

- Currently have any of the nonplaque forms of psoriasis: erythrodermic, guttate, or pustular.
- Currently have drug induced psoriasis (new onset or exacerbation of psoriasis from beta blockers, calcium channel blockers, or lithium).
- Men who are planning to initiate a pregnancy while enrolled in the study or for 3 months following completion of the study.
- Women of child bearing potential are not allowed in the study.
- Used any investigational drug within the previous 4 weeks.
- Recent previous treatment with anti TNF α therapy (or other biological therapy), immunosuppressive agents such as cyclosporine, mycophenolate, pimecrolimus, or tacrolimus. The following washout period will be required for such patients to be eligible to participate in the trial.
    1. 2 months washout prior to screening for etanercept, adalimumab, or infliximab.
    2. 1 month washout prior to screening for cyclosporine, mycophenolate, tacrolimus, and any systemic immunosuppressants including, but not limited to, methotrexate, azathioprine, 6 thioguanine, mercaptopurine, and hydroxyurea

Other protocol defined inclusion/exclusion criteria may apply

Ages Eligible for Study

18 Years to 75 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Basic Science
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Care Provider)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: AIN457 AIN457A 3mg/kg was administered intravenously as a single dose.	Biological: AIN457 • single infusion of 3 mg/kg
Placebo Comparator: Placebo Placebo was administered intravenously as a single dose.	Drug: Placebo • single infusion of placebo

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percent Change From Baseline in Psoriasis Area and Severity Index (PASI) Mean Score	The PASI assessed the extent of psoriasis on four body surface areas (head, trunk and upper limbs) and the degree of plaque erythema, scaling and thickness. The PASI score accounted for the extent of body surface area affected by the erythema, scaling and thickness and the severity of these measures. The score ranged from 0 (no disease) to 72 (maximal disease) where a reduction in PASI score from baseline indicates improvement. The percentage change was calculated by subtracting the week 4 values from the baseline values.The percentage change was calculated for each	Baseline, Week 4

	entire treatment group (not for each participant). A positive percentage change from baseline indicates improvement.	
Percentage of Participants With Change From Baseline in Investigators Global Assessment (IGA) Score	The IGA is an instrument which captured and categorized the global assessment of all clinical signs and symptoms of disease. The investigator used all available information for the assessment, including subjective information from the participant and (where available) photographs taken at baseline. The IGA categories were clear, almost clear, mild disease, moderate disease, severe disease and very severe disease. This outcome measure shows the percentage of patients who experienced a category change from baseline. Category changes of 1, 2 or 3 indicate improvement.	Baseline, Week 4

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Pharmacokinetics of AIN457: Time to Reach the Maximum Concentration After Drug Administration (Tmax)	Blood was drawn for PK analyses at baseline (prior to dosing), end of infusion, 1 hr and 2 hr after infusion, and during office visits in Weeks 1, 2, 3, 4, 5, 6, 8, 12, 16, 20 and 26. The PK samples may have been taken at any time during each office visit, following the day of study drug infusion. This outcome measure shows the mean of all values resulting from each time point outlined above.	Day 182
Pharmacokinetics of AIN457: Observed Maximum Serum Concentration Following Drug	Blood was drawn for PK analyses at baseline (prior to dosing), end of infusion, 1 hr and 2 hr after infusion, and during office visits in Weeks 1, 2, 3, 4, 5, 6, 8, 12, 16, 20 and 26. The PK samples may have been taken at any time during each office visit, following the day of study drug infusion. This outcome measure	Day 182

Administration (Cmax)	shows the mean of all values resulting from each time point outlined above.	
Pharmacokinetics of AIN457: Area Under the Serum Concentration-time Cure From Time Zero to the Time of Last Quantifiable Concentration (AUClast), Area Under the Serum Concentration-time Curve From Time Zero to (AUCinf)	Blood was drawn for PK analyses at baseline (prior to dosing), end of infusion, 1 hr and 2 hr after infusion, and during office visits in Weeks 1, 2, 3, 4, 5, 6, 8, 12, 16, 20 and 26. The PK samples may have been taken at any time during each office visit, following the day of study drug infusion. This outcome measure shows the mean of all values resulting from each time point outlined above.	Day 182
Pharmacokinetics of AIN457: Volume of Distribution During the Terminal Phase Following Intravenous Elimination (Vz)	Blood was drawn for PK analyses at baseline (prior to dosing), end of infusion, 1 hr and 2 hr after infusion, and during office visits in Weeks 1, 2, 3, 4, 5, 6, 8, 12, 16, 20 and 26. The PK samples may have been taken at any time during each office visit, following the day of study drug infusion. This outcome measure shows the mean of all values resulting from each time point outlined above.	Day 182
Pharmacokinetics of AIN457: Systemic Clearance From Serum Following Intravenous Administration (CL)	Blood was drawn for PK analyses at baseline (prior to dosing), end of infusion, 1 hr and 2 hr after infusion, and during office visits in Weeks 1, 2, 3, 4, 5, 6, 8, 12, 16, 20 and 26. The PK samples may have been taken at any time during each office visit, following the day of study drug infusion. This outcome measure shows the mean of all values resulting from each time point outlined above.	Day 182

Pharmacokinetics of AIN457: Terminal Elimination Half-life (T1/2)	Blood was drawn for PK analyses at baseline (prior to dosing), end of infusion, 1 hr and 2 hr after infusion, and during office visits in Weeks 1, 2, 3, 4, 5, 6, 8, 12, 16, 20 and 26. The PK samples may have been taken at any time during each office visit, following the day of study drug infusion. This outcome measure shows the mean of all values resulting from each time point outlined above.	Day 182

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Novartis Pharmaceuticals

Collaborators

No information provided

Investigators

- Study Director: Novartis Pharmaceuticals, Novartis Pharmaceuticals

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

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Study Registration Dates

First Submitted
2008-04-29

First Submitted that Met QC Criteria
2008-04-30

First Posted (Estimated)
2008-05-01

Results Reporting Dates

Results First Submitted
2015-01-28

Results First Submitted that Met QC Criteria
2015-04-09

Results First Posted (Estimated)
2015-04-10

Study Record Updates

Last Update Submitted that met QC Criteria
2015-04-09

Last Update Posted (Estimated)
2015-04-10

Last Verified
2015-04

More Information

Terms related to this study

Keywords Provided by Novartis (Novartis Pharmaceuticals)

Plaque psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

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COMPLETED

A Safety, Tolerability, Pharmacokinetics And Pharmacodynamics Study Of PF-06700841, With Bioavailability/ Food Effect Investigation

ClinicalTrials.gov ID: NCT02310750

Sponsor: Pfizer

Information provided by: Pfizer (Responsible Party)

Last Update Posted: 2017-03-08

Study Details Tab

Study Overview

Brief Summary

The main purpose of the study is to determine if PF-06700841 is safe and well tolerated when administered to humans. A secondary purpose is to assess what the body does to PF-06700841 and to assess what PF-06700841 does to the body when given as single and multiple doses. The pharmacokinetic properties of different forms of PF-06700841 may be studied (tablet and solution/suspension forms).

Official Title

A Phase 1, Within Cohort, Randomized, Double Blind, Third-party Open, Placebo-controlled, Single- And Multiple Dose Escalation, Parallel Group Study To Evaluate The Safety, Tolerability, Pharmacokinetics And Pharmacodynamics Of PF-06700841 In Healthy Subjects And Subjects With Plaque Psoriasis And Bioavailability Of A Tablet Formulation Relative To Suspension Formulation And The Effect Of Food On A Tablet Formulation Of PF-06700841

Conditions

Plaque Psoriasis

Intervention / Treatment

- Drug: PF-06700841 oral solution/suspension
- Other: Placebo
- Drug: PF-06700841 tablet

Other Study ID Numbers

- B7931001

Study Start

2014-11

Primary Completion (Actual)

2016-01

Study Completion (Actual)

2016-02

Enrollment (Actual)

96

Study Type

Interventional

Phase

Phase 1

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Other U.S. FDA Resources (https://clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

California Locations

Anaheim, California, United States, 92801
Anaheim Clinical Trials, LLC



Feedback

Participation Criteria

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Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/ct2/about-studies/learn#ParticipatingInResearch).

Eligibility Criteria

Description

Inclusion Criteria:

Key Inclusion Criteria for Healthy Subject Cohorts:

- Healthy male subjects and/or female subjects of non-childbearing potential between the ages of 18 and 55 years, inclusive
- No evidence of active or latent or inadequately treated infection with Mycobacterium tuberculosis (TB)

Key Inclusion Criteria for Psoriasis Subject Cohorts:

- Male subjects and/or female subjects of non-childbearing potential with a diagnosis of plaque psoriasis who are between the ages of 18 and 65 years, inclusive
- Have a diagnosis of plaque psoriasis for at least 6 months prior to first study dose

Exclusion Criteria:

Key Exclusion Criteria for Healthy Subject Cohorts:

- Evidence or history of clinically significant hematological, renal, endocrine, pulmonary, gastrointestinal, cardiovascular, hepatic, psychiatric, neurologic, or allergic disease (including drug allergies, but excluding untreated, asymptomatic, seasonal allergies at time of dosing)
- Males of childbearing potential who are unwilling or unable to use a highly effective method of contraception as outlined in this protocol for the duration of the study and for at least 28 days after the last dose of investigational product

Key Exclusion Criteria for Psoriasis Subject Cohorts:

- Currently have non plaque forms of psoriasis, (eg, erythrodermic, guttate, or pustular psoriasis).
- Have current drug induced psoriasis, eg, a new onset of psoriasis or an exacerbation of psoriasis from beta blockers, calcium channel blockers, antimalarial drugs or lithium
- Males of childbearing potential who are unwilling or unable to use a highly effective method of contraception as outlined in this protocol for the duration of the study and for at least 28 days after the last dose of investigational product

Ages Eligible for Study

18 Years to 65 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

Yes

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Triple (Participant, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: PF-06700841 Oral Solution/Suspension	Drug: PF-06700841 oral solution/suspension • Oral solution or suspension of study drug PF-06700841 (once daily or twice daily during multiple dosing periods)
Experimental: PF-06700841 Tablet	Drug: PF-06700841 tablet • PF-06700841 tablet formulation administered during the bioavailability / food effect investigation
Placebo Comparator: Placebo Oral placebo comparator for the healthy subject single and multiple ascending dose periods, and the psoriasis multiple dose period. No placebo used for the bioavailability investigation.	Other: Placebo • Matching placebo given during the single ascending and multiple dose periods.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Single Ascending Dose (SAD) Cohort: Change From Baseline in Blood Pressure at Day 1		Baseline, 24 hours post-dose on Day 1
Multiple Ascending Dose (MAD) Cohort: Change From Baseline in Blood Pressure at Day 10		Baseline, 16 hours post-dose on Day 10
Multiple Ascending Dose (MAD) Psoriasis Cohort: Change From Baseline in Blood Pressure at Day 28		Baseline, 16 hours post-dose on Day 28
Single Ascending Dose (SAD) Cohort: Change From Baseline in Pulse Rate at Day 1		Baseline, 24 hours post-dose on Day 1
Multiple Ascending Dose (MAD) Cohort: Change From Baseline in Pulse Rate at Day 10		Baseline, 16 hours post-dose on Day 10
Multiple Ascending Dose (MAD) Psoriasis Cohort: Change From Baseline in Pulse Rate at Day 28		Baseline, 16 hours post-dose on Day 28

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Single Ascending Dose (SAD) Cohort: Change From Baseline in Oral Temperature at Day 1		Baseline, 24 hours post-dose on Day 1
Multiple Ascending Dose (MAD) Cohort: Change From Baseline in Oral Temperature at Day 10		Baseline, 16 hours post-dose on Day 10
Multiple Ascending Dose (MAD) Psoriasis Cohort: Change From Baseline in Oral Temperature at Day 28		Baseline, 16 hours post-dose on Day 28
Number of Participants With Change From Baseline in Physical Examinations	Physical examinations included head, ears, eyes, nose, mouth, skin, heart and lung examinations, lymph nodes, gastrointestinal, musculoskeletal, and neurological systems.	SAD Cohort: Baseline up to Day 8, MAD Cohort: Baseline up to Day 28, MAD Psoriasis Cohort: Baseline up to Day 56, Food Effect Cohort: Baseline up to Day 37
Single Ascending Dose (SAD) Cohort: Change From Baseline in 12-Lead Electrocardiogram (ECG) Parameters (PR Interval, QRS Complex, QT Interval, QTC Interval) at Day 1		Baseline, 24 hours post-dose on Day 1
Multiple Ascending Dose (MAD) Cohort: Change From Baseline in 12-Lead Electrocardiogram (ECG) Parameters (PR Interval, QRS Complex, QT Interval, QTC Interval) at Day 10		Baseline, 16 hours post-dose on Day 10
Multiple Ascending Dose (MAD) Psoriasis Cohort: Change From Baseline in 12-Lead Electrocardiogram (ECG) Parameters (PR Interval, QRS Complex, QT Interval, QTC Interval) at Day 28		Baseline, 16 hours post-dose on Day 28
Single Ascending Dose (SAD) Cohort: Change From Baseline in Heart Rate at Day 1		Baseline, 24 hours post-dose on Day 1
Multiple Ascending Dose (MAD) Cohort: Change From Baseline in Heart Rate at Day 10		Baseline, 16 hours post-dose on Day 10
Multiple Ascending Dose (MAD) Psoriasis Cohort: Change From Baseline in Heart Rate at Day 28		Baseline, 16 hours post-dose on Day 28
Number of Participants With Treatment-Emergent Adverse Events (AEs), Serious Adverse Events (SAEs) and Discontinuation Due to AEs	An AE was any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. An SAE is an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent were events between first dose of study drug up to the end of study (up to Day 8 in SAD cohort, Day 28 in MAD cohort, Day 56 in MAD Psoriasis cohort, Day 37 in Food effect cohort), that were absent before treatment or that worsened relative to pretreatment state. AEs included both SAE and non-SAE.	SAD Cohort: Baseline up to Day 8, MAD Cohort: Baseline up to Day 28, MAD Psoriasis Cohort: Baseline up to Day 56, Food Effect Cohort: Baseline up to Day 37
Number of Adverse Events (AEs) According to Severity	An AE was any untoward medical occurrence attributed to study drug in a participant who received study drug. AEs were classified according to the severity in 3 categories a) mild - AEs does not interfere with participant's usual function b) moderate - AEs interferes to some extent with participant's usual function c) severe - AEs interferes significantly with participant's usual function.	SAD Cohort: Baseline up to Day 8, MAD Cohort: Baseline up to Day 28, MAD Psoriasis Cohort: Baseline up to Day 56, Food Effect Cohort: Baseline up to Day 37
Number of Participants With Laboratory Abnormalities	Criteria for abnormality:hematology: hemoglobin, hematocrit, red blood cell count: less than(<) 0.8*lower limit of normal (LLN); mean corpuscular volume; mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration: <0.9*LLN,>1.1*upper limit of normal (ULN); platelets: <0.5*LLN,>1.75*ULN, white blood cell count: <0.6*LLN, >1.5*ULN; lymphocytes, total neutrophils: <0.8*LLN, >1.2*ULN; eosinophils, basophils, monocytes: >1.2*ULN; coagulation: activated partial thromboplastin time, prothrombin, prothrombin international ratio: >1.1*ULN; liver function: bilirubin: >1.5*ULN; aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase: >3.0*ULN; protein, albumin: <0.8*LLN></D>1.2*ULN; renal function:blood urea nitrogen,creatinine: >1.3*ULN; uric acid: >1.2*ULN, electrolytes: sodium, potassium, chloride, calcium, bicarbonate: <0.9*LLN,>1.1*ULN; urinalysis: pH<4.5, >8; glucose, protein, blood, ketones, urobilinogen, bilirubin, nitrite; Other(glucose: <0.6*LLN,>1.5*ULN)	SAD Cohort: Baseline up to Day 8, MAD Cohort: Baseline up to Day 28, MAD Psoriasis Cohort: Baseline up to Day 56, Food Effect Cohort: Baseline up to Day 37
Single Ascending Dose (SAD) Cohort: Change From Baseline in Creatinine Clearance at Day 1	Creatinine clearance is a measure of kidney function. Creatinine clearance is the volume of blood plasma that is cleared of creatinine by the kidneys per unit time.	Baseline, 24 hours post-dose on Day 1
Multiple Ascending Dose (MAD) and MAD Psoriasis Cohort: Change From Baseline in Creatinine Clearance at Day 10	Creatinine clearance is a measure of kidney function. Creatinine clearance is the volume of blood plasma that is cleared of creatinine by the kidneys per unit time.	Baseline, 16 hours post-dose on Day 10
Multiple Ascending Dose (MAD) Psoriasis Cohort: Change From Baseline in Creatinine Clearance at Day 28	Creatinine clearance is a measure of kidney function. Creatinine clearance is the volume of blood plasma that is cleared of creatinine by the kidneys per unit time.	Baseline, 16 hours post-dose on Day 28
Food Effect Cohort: Area Under the Plasma Concentration-Time Curve From Time Zero Extrapolated to Infinite Time (AUCinf) of PF-06700841	AUCinf = Area under the plasma concentration versus time curve (AUC) from time zero (pre-dose) to extrapolated infinite time (0-inf)	Pre-dose, 0.5, 1, 2, 4, 6, 8, 12, 16, 24, 36, 48, 72 hours post dose on Day 1
Food Effect Cohort: Area Under the Curve From Time Zero to Last Quantifiable Concentration (AUClast) of PF-06700841	Area under the plasma concentration time-curve from time zero to the time of last measured concentration (AUClast).	pre-dose, 0.5, 1, 2, 4, 6, 8, 12, 16, 24, 36, 48, 72 hours post dose on Day 1
Food Effect Cohort: Maximum Observed Plasma Concentration (Cmax) of PF-06700841		pre-dose, 0.5, 1, 2, 4, 6, 8, 12, 16, 24, 36, 48, 72 hours post dose on Day 1

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Single Ascending Dose (SAD), Multiple Ascending Dose (MAD) and MAD Psoriasis Cohort: Maximum Observed Plasma Concentration (Cmax) of PF-06700841		SAD: pre-dose, 0.5,1,2,4,6,8,12,16,24,36,48,72,96 hour post dose on Day 1; MAD: pre-dose 0.5,1,2,4,6,8,12,24 hour post-dose on Day 10; MAD Psoriasis: pre-dose, 0.5,1,2,4,6,8,12,16,24 hours post dose on Day 28
Single Ascending Dose (SAD), Multiple Ascending Dose (MAD) and MAD Psoriasis Cohort: Time to Reach Maximum Observed Plasma Concentration (Tmax) of PF-06700841		SAD: pre-dose, 0.5,1,2,4,6,8,12,16,24,36,48,72,96 hour post dose on Day 1; MAD: pre-dose 0.5,1,2,4,6,8,12,24 hour post-dose on Day 10; MAD Psoriasis: pre-dose, 0.5,1,2,4,6,8,12,16,24 hours post dose on Day 28

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Food Effect Cohort: Time to Reach Maximum Observed Plasma Concentration (Tmax) of PF-06700841		Pre-dose, 0.5, 1, 2, 4, 6, 8, 12, 16, 24, 36, 48, 72 hours post dose on Day 1
Single Ascending Dose (SAD) Cohort: Area Under the Plasma Concentration-Time Curve From Time Zero Extrapolated to Infinite Time (AUCinf) of PF-06700841	AUCinf = Area under the plasma concentration versus time curve (AUC) from time zero (pre-dose) to extrapolated infinite time (0-inf).	pre-dose, 0.5, 1, 2, 4, 6, 8, 12, 16, 24, 36, 48, 72, 96 hour post dose on Day 1
Multiple Ascending Dose (MAD) and MAD Psoriasis Cohort: Area Under the Curve From Time Zero to End of Dosing Interval (AUCtau) of PF-06700841	Area under the plasma concentration versus time curve from time 0 to end of dosing interval (AUCtau), where dosing interval was 24 hours for MAD once daily cohorts, 12 hours for MAD twice daily cohort and 24 hours for MAD Psoriasis cohort.	MAD: pre-dose 0.5, 1, 2, 4, 6, 8, 12, 24 hour post-dose on Day 10; MAD Psoriasis: pre-dose, 0.5,1,2,4,6,8,12,16,24 hours post dose on Day 28
Single Ascending Dose (SAD) Cohort: Area Under the Curve From Time Zero to Last Quantifiable Concentration (AUClast) of PF-06700841	Area under the plasma concentration time-curve from time zero to the time of last measured concentration (AUClast).	pre-dose, 0.5, 1, 2, 4, 6, 8, 12, 16, 24, 36, 48, 72, 96 hour post dose on Day 1
Single Ascending Dose (SAD), Multiple Ascending Dose (MAD) and MAD Psoriasis Cohort: Dose Normalized Maximum Observed Plasma Concentration (Cmax[dn]) of PF-06700841	Dose normalized (dn) Cmax was calculated by dividing Cmax by the exact dose of PF-06700841 (in mg) administered to a participant.	SAD: pre-dose, 0.5,1,2,4,6,8,12,16,24,36,48,72,96 hour post dose on Day 1; MAD: pre-dose 0.5,1,2,4,6,8,12,24 hour post-dose on Day 10; MAD Psoriasis: pre-dose, 0.5,1,2,4,6,8,12,16,24 hours post dose on Day 28
Single Ascending Dose (SAD) Cohort: Dose Normalized Area Under the Plasma Concentration-Time Profile From Time Zero Extrapolated to Infinite Time (AUCinf[dn]) of PF-06700841	AUCinf = Area under the plasma concentration versus time curve (AUC) from time zero (pre-dose) to extrapolated infinite time (0-inf). AUCinf(dn) was calculated by dividing AUCinf by the exact dose of PF-06700841 (in mg) administered to a participant.	pre-dose, 0.5, 1, 2, 4, 6, 8, 12, 16, 24, 36, 48, 72, 96 hour post dose on Day 1
Single Ascending Dose (SAD) Cohort: Dose Normalized Area Under the Curve From Time Zero to Last Quantifiable Concentration (AUClast[dn]) of PF-06700841	Area under the plasma concentration time-curve from time zero to the time of last measured concentration (AUClast). AUClast(dn) was calculated by dividing AUClast by the exact dose of of PF-06700841 (in mg) administered to a participant.	Pre-dose, 0.5, 1, 2, 4, 6, 8, 12, 16, 24, 36, 48, 72, 96 hour post dose on Day 1
Multiple Ascending Dose (MAD) Cohort: Dose Normalized Area Under the Curve From Time Zero to End of Dosing Interval (AUCtau[dn]) of PF-06700841	Area under the concentration curve from time 0 to end of dosing interval (AUCtau), where dosing interval was 24 hours for MAD once daily cohorts, 12 hours for MAD twice daily cohort. AUCtau(dn) was calculated by dividing AUCtau by the exact dose of of PF-06700841 (in mg) administered to a participant.	pre-dose 0.5,1,2,4,6,8,12,24 hour post-dose on Day 10
Single Ascending Dose (SAD), Multiple Ascending Dose (MAD) and MAD Psoriasis Cohort: Plasma Decay Half-Life (t1/2) of PF-06700841	Plasma decay half-life is the time measured for the plasma concentration of PF-06700841 to decrease by one half.	SAD: pre-dose, 0.5,1,2,4,6,8,12,16,24,36,48,72,96 hour post-dose on Day 1; MAD: pre-dose 0.5,1,2,4,6,8,12,24 hour post-dose on Day 10; MAD Psoriasis: pre-dose, 0.5,1,2,4,6,8,12,16,24 hours post-dose on Day 28
Single Ascending Dose (SAD), Multiple Ascending Dose (MAD) and MAD Psoriasis Cohort: Mean Residence Time (MRT) of PF-06700841	MRT= AUMCinf/AUCinf, where AUMCinf is the area under the first moment curve from time 0 extrapolated to infinite time, calculated using the linear/log trapezoidal method.	SAD: pre-dose, 0.5, 1, 2, 4, 6, 8, 12, 16, 24, 36, 48, 72, 96 hour post-dose on Day 1; MAD: pre-dose 0.5, 1, 2, 4, 6, 8, 12, 24 hour post-dose on Day 10; MAD Psoriasis: pre-dose, 0.5, 1, 2, 4, 6, 8, 12, 16, 24 hours post-dose on Day 28
Single Ascending Dose (SAD), Multiple Ascending Dose (MAD) and MAD Psoriasis Cohort: Apparent Volume of Distribution (Vz/F) of PF-06700841	Volume of distribution is defined as the theoretical volume in which the total amount of drug would need to be uniformly distributed to produce the desired plasma concentration of a drug. Apparent volume of distribution after oral dose (Vz/F) is influenced by the fraction absorbed.	SAD: pre-dose, 0.5, 1, 2, 4, 6, 8, 12, 16, 24, 36, 48, 72, 96 hour post-dose on Day 1; MAD: pre-dose 0.5, 1, 2, 4, 6, 8, 12, 24 hour post-dose on Day 10; MAD Psoriasis: pre-dose, 0.5, 1, 2, 4, 6, 8, 12, 16, 24 hours post-dose on Day 28
Single Ascending Dose (SAD), Multiple Ascending Dose (MAD) and MAD Psoriasis Cohort: Apparent Clearance (CL/F) of PF-06700841	Drug clearance is a quantitative measure of the rate at which a drug substance is removed from the blood. Clearance obtained after oral dose is influenced by the fraction of the dose absorbed. CL/F =Dose of PF-06700841/AUCinf.	SAD: pre-dose, 0.5, 1, 2, 4, 6, 8, 12, 16, 24, 36, 48, 72, 96 hour post-dose on Day 1; MAD: pre-dose 0.5, 1, 2, 4, 6, 8, 12, 16, 24 hour post-dose on Day 10; MAD Psoriasis: pre-dose, 0.5, 1, 2, 4, 6, 8, 12, 16, 24 hours post-dose on Day 28
Multiple Ascending Dose (MAD) and MAD Psoriasis Cohort: Peak-Trough Fluctuation (PTF) of PF-06700841	PTF was calculated as: Cmax-Cmin/Cavg. Cmax is the maximum observed plasma concentration of PF-06700841. Cmin is the minimum observed plasma concentration of PF-06700841. Cavg is the average observed plasma concentration of PF-06700841 calculated as area under the plasma concentration-time curve during a dosing interval (AUC[tau]) divided by the dosing interval (tau), where dosing interval was 24 hours for MAD once daily cohorts, 12 hours for MAD twice daily cohort and 24 hours for MAD Psoriasis cohort.	MAD: pre-dose 0.5, 1, 2, 4, 6, 8, 12, 24 hour post-dose on Day 10; MAD Psoriasis: pre-dose, 0.5,1,2,4,6,8,12,16,24 hours post-dose on Day 28
Multiple Ascending Dose (MAD) Cohort: Amount of PF-06700841 Recovered Unchanged in the Urine Over the Time Interval Tau (Aetau)	Aetau is the amount of drug recovered unchanged in urine during the dosing interval (tau), where dosing interval was 24 hours for MAD once daily cohorts, 12 hours for MAD twice daily cohort.	0-24 hour on Day 10
Multiple Ascending Dose (MAD) Cohort: Percentage of Dose of PF-06700841 Recovered Unchanged in the Urine Over the Time Interval Tau (Aetau%)	Aetau% was calculated as: 100*Aetau/dose. Aetau is the amount of drug recovered unchanged in urine during the dosing interval (tau), where dosing interval was 24 hours for MAD once daily cohorts, 12 hours for MAD twice daily cohort.	0-24 hours on Day 10
Multiple Ascending Dose (MAD) Cohort: Renal Clearance	Renal clearance was calculated as amount of drug recovered unchanged in urine during the dosing interval tau (Aetau) divided by area under the plasma concentration time-curve from time zero to end of dosing interval (AUCtau), where dosing interval was 24 hours for MAD once daily cohorts, 12 hours for MAD twice daily cohort.	0-24 hours on Day 10
Single Ascending Dose (SAD) Cohort: Interferon Gamma-Induced Protein 10 (IP-10) Concentration in Serum at Baseline	Serum samples for IP-10 were analyzed using a validated analytical assay. Lower limit of quantification (LLOQ) for IP-10 was 10 pg/mL.	Baseline
Multiple Ascending Dose (MAD) Cohort: Change From Baseline in Interferon Gamma-Induced Protein 10 (IP-10) Concentration in Serum at Day 2, 5, 10, 11, 28	Serum samples for IP-10 were analyzed using a validated analytical assay. LLOQ for IP-10 was 10 pg/mL.	Baseline, Day 2, 5, 10, 11, 28

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Multiple Ascending Dose (MAD) Psoriasis Cohort: Change From Baseline in Interferon Gamma-Induced Protein 10 (IP-10) Concentration in Serum at Day 2, 5, 7, 14, 21, 28, 29, 35, 56	Serum samples for IP-10 were analyzed using a validated analytical assay. Lower limit of quantification (LLOQ) for IP-10 was 10 pg/mL.	Baseline, Day 2, 5, 7, 14, 21, 28, 29, 35, 56
Single Ascending Dose (SAD) Cohort: High Sensitivity C-reactive Protein (hsCRP) Concentration in Serum at Baseline	Serum samples for hsCRP were analyzed using a validated analytical assay. Reference range for measurement of CRP was 0.015 to 2.0 mg/dL. LLOQ for hsCRP was 0.03 mg/dL and limit of detection was 0.015 mg/dL.	Baseline
Multiple Ascending Dose (MAD) Cohort: Change From Baseline in High Sensitivity C-reactive Protein (hsCRP) at Day 2, 5, 10, 11, 28	Serum samples for hsCRP were analyzed using a validated analytical assay. Reference range for measurement of CRP was 0.015 to 2.0 mg/dL. LLOQ for hsCRP was 0.03 mg/dL and limit of detection was 0.015 mg/dL.	Baseline, Day 2, 5, 10, 11, 28
Multiple Ascending Dose (MAD) Psoriasis Cohort: Change From Baseline in High Sensitivity C-reactive Protein (hsCRP) at Day 2, 5, 7, 14, 21, 28, 29, 35 and 56	Serum samples for hsCRP were analyzed using a validated analytical assay. Reference range for measurement of CRP was 0.015 to 2.0 mg/dL. LLOQ for hsCRP was 0.03 mg/dL and limit of detection was 0.015 mg/dL.	Baseline, Day 2, 5, 7, 14, 21, 28, 29, 35, 56
Single Ascending Dose (SAD) Cohort: Change From Baseline in Neutrophil Counts at Day 2, 5 and 8		Baseline, Day 2, 5, 8
Multiple Ascending Dose (MAD) Cohort: Change From Baseline in Neutrophil Counts at Day 4, 8, 10, 11, 14, 28		Baseline, Day 4, 8, 10, 11, 14, 28
Multiple Ascending Dose (MAD) Psoriasis Cohort: Change From Baseline in Neutrophil Counts at Day 4, 6, 8, 10, 13, 14, 21, 28, 35, 42 and 56		Baseline, Day 4, 6 ,8,10, 13, 14, 21, 28, 35, 42, 56
Single Ascending Dose (SAD) Cohort: Change From Baseline in Reticulocyte Counts at Day 2, 5, 8		Baseline, Day 2, 5, 8
Multiple Ascending Dose (MAD) Cohort: Change From Baseline in Reticulocyte Counts at Day 4, 8, 10, 11, 14 and 28		Baseline, Day 4, 8, 10, 11, 14, 28
Multiple Ascending Dose (MAD) Psoriasis Cohort: Change From Baseline in Reticulocyte Counts at Day 4, 6, 8, 10, 13, 14, 21, 28, 35, 42 and 56		Baseline, Day 4, 6 ,8,10, 13, 14, 21, 28, 35, 42, 56

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Pfizer

Collaborators

No information provided

Investigators

- Study Director: Pfizer CT.gov Call Center, Pfizer

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

Publications

No publications available

* Find Publications about Study Results and related Journal Publications in the "Results" section of the study record.

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2014-11-18

First Submitted that Met QC Criteria
2014-12-04

First Posted (Estimated)
2014-12-08

Results Reporting Dates

Results First Submitted
2017-01-13

Results First Submitted that Met QC Criteria
2017-01-13

Results First Posted
2017-03-08

Study Record Updates

Last Update Submitted that met QC Criteria
2017-01-13

Last Update Posted
2017-03-08

Last Verified
2017-01

More Information

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Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Protein Kinase Inhibitors
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action
PF-06700841

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by Pfizer

To provide feedback or information for a study posted, you can click here. https://trialresult.pfizer.com/pages/landing.aspx?StudyID=B7041001&StudyName=A%20Phase%201%2C%20Within%20Cohort%2C%20Randomized%2C%20Double%20Blind%2C%20Third-party%20Open%2C%20Placebo-controlled%2C%20Single%20And%20Multiple%20Dose%20Escalation%2C%20Study%20To%20Evaluate%20The%20Safety%2C%20Tolerability%2C%20Pharmacokinetics%20And%20Pharmacodynamics%20Of%20PF-06700841%20In%20Healthy%20Subjects%20And%20Subjects%20With%20Plaque%20Psoriasis%20And%20Bioavailability%20Of%20A%20Phase%20Formulation%20Relative%20To%20Assessment%20Formulation%20And%20The%20Effect%20Of%20Food%20On%20Bioavailability%20Of%20PF-06700841

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Go to the classic website

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

A Study of the Safety and Efficacy of Ustekinumab in Adolescent Patients With Psoriasis (CADMUS)

ClinicalTrials.gov ID NCT01090427

Sponsor Janssen Research & Development, LLC

Information provided by Janssen Research & Development, LLC (Responsible Party)

Last Update Posted 2015 01 29

Study Details Tab

Study Overview

Brief Summary

This is a study of the safety and efficacy of ustekinumab (CNTO 1275) in adolescent patients with moderate to severe psoriasis.

Feedback

Detailed Description

This is a randomized (drug assigned by chance), double blind (a medical research study in which neither the researchers nor the participants know what treatment the participant is receiving), placebo controlled, parallel (a medical research study comparing the response in two or more groups of participants receiving different treatments), multicenter of ustekinumab in adolescent participants with moderate to severe psoriasis. The total duration of study will be 60 weeks. The study will consists of 2 parts; a Screening period and a Treatment period. In treatment period participants will receive either ustekinumab half standard dosage, ustekinumab standard dosage or Placebo. Participants receiving ustekinumab half standard dosage and ustekinumab standard dosage at Week 0, will receive placebo at Week 12 and participants receiving placebo at Week 0 will be randomly assigned to either ustekinumab half standard dosage or ustekinumab standard dosage Weeks 12, 16, 28, and 40. Primarily efficacy will be evaluated by physician s global assessment (PGA) score of cleared or minimal disease. Participants safety will be monitored throughout the study.

Official Title

A Phase 3 Multicenter, Randomized, Double blind, Placebo controlled Study Evaluating the of Efficacy and Safety of Ustekinumab in the Treatment of Adolescent Subjects With Moderate to Severe Plaque type Psoriasis (CADMUS)

Conditions

Psoriasis

Intervention / Treatment

- Drug: Ustekinumab Half Standard Dosage
- Drug: Ustekinumab Standard Dosage
- Other: Placebo

Other Study ID Numbers

- CR017053
- CNTO1275PSO3006 (Other Identifier) (OTHER: Janssen Research & Development, LLC)
- CADMUS (Other Identifier) (OTHER: Janssen Research & Development, LLC)
- 2009 014368 20 (EudraCT Number)

Study Start

2010 05

Primary Completion (Actual)

2013 01

Study Completion (Actual)

2014 01

Enrollment (Actual)

110

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Ustekinumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Ustekinumab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Belgium

- Brussel, Belgium
- Gent, Belgium
- Liege, Belgium

Click to view interactive map

Canada

Quebec, Canada

Alberta Locations

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Have a diagnosis of plaque type psoriasis with or without psoriatic arthritis (PsA) for at least 6 months
- Are candidates for phototherapy or systemic treatment of psoriasis
- Have screening laboratory test results within the study parameters

Exclusion Criteria:

- Currently have nonplaque forms of psoriasis
- Have used any therapeutic agent targeted at reducing interleukin 12 (IL 12) or interleukin 23 (IL 23), including but not limited to ustekinumab and briakinumab
- Received conventional systemic therapies or phototherapy within the last 4 weeks
- Received biologic therapies within the last 3 months

Ages Eligible for Study

12 Years to 18 Years (Child, Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Ustekinumab Half-standard Dosage Participants will receive ustekinumab at half the standard dosage at Weeks 0, 4, 16, 28, and 40. In addition, all participants will receive a single SC dose of placebo at Week 12.	Drug: Ustekinumab - Half-Standard Dosage • Ustekinumab 0.375 mg/kg, 22.5 mg, or 45 mg based on body weight, administered subcutaneously (under the skin) at Weeks 0, 4, 16, 28, and 40. Other: Placebo • Placebo administered subcutaneously at Weeks 0 and 4 or at Week 12.
Experimental: Ustekinumab Standard Dosage Participants will receive ustekinumab at the standard dosage at Weeks 0, 4, 16, 28, and 40. In addition, all participants will receive a single SC dose of placebo at Week 12.	Drug: Ustekinumab - Standard Dosage • Ustekinumab 0.75 mg/kg, 45 mg, or 90 mg based on body weight administered subcutaneously at Weeks 0, 4, 16, 28, and 40. Other: Placebo • Placebo administered subcutaneously at Weeks 0 and 4 or at Week 12.
Experimental: Placebo Participants will receive matching placebo at Week 0 and 4, followed by ustekinumab at half-	Other: Placebo • Placebo administered subcutaneously at Weeks 0 and 4 or at Week 12.

standard or standard dosage at Weeks 12, 16, 28, and 40.	

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Percentage of Participants Achieving a Physicians Global Assessment (PGA) Score of Cleared (0) or Minimal (1) at Week 12	The PGA documents the physician s assessment of the participant s psoriasis status according to the following categories: induration, scaling, and erythema. The participant s psoriasis is assessed as 5-point scale as follows: cleared (0), minimal (1), mild (2), moderate (3), or severe (4); higher score indicates worse disease. The table below shows the percentage of participants who achieved a PGA score of 0 or 1 at Week 12 in each treatment group.	Week 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Percentage of Participants Achieving a Psoriasis Area and Severity Index (PASI) 75 Response at Week 12	The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 to 72, with higher scores indicating worse disease. A PASI 75 response is defined as a equal to or greater than (=>) 75% improvement in PASI score from baseline. The table below shows the percentage of participants who achieved a PASI 75 response at Week 12 in each treatment group.	Week 12

Change From Baseline in Childrens Dermatology Life Quality Index (CDLQI) Score at Week 12 Compared Between the Placebo Group and the Ustekinumab Treatment Groups	The CDLQI is a dermatology-specific quality of life instrument designed to assess the impact of the disease on a childs quality of life. The CDLQI, a 10-item questionnaire has 4 items response options and a recall period of 1 week. In addition to evaluating overall quality of life, the CDLQI can be used to assess 6 different aspects that may affect quality of life: symptoms and feelings, leisure, School or holidays, personal relationships, sleep, and treatment. The CDLQI is calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0; the higher the score, the greater impairment in quality of life. The table below shows the mean change in CDLQI score from baseline at Week 12 for each treatment group.	Baseline; Week 12
The Percentage of Participants Achieving a Psoriasis Area and Severity Index (PASI) 90 Response at Week 12 Compared Between the Placebo Group and the Ustekinumab Treatment Groups	The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 to 72, with higher scores indicating worse disease. The table below shows the percentage of participants who achieved a PASI 90 response defined as achieving a greater than or equal to (≥) 90% improvement in PASI score from baseline.	Week 12
The Percentage of Participants Achieving a Physicians Global Assessment (PGA) Score of	The PGA documents the physicians assessment of the participants psoriasis status according to the following categories: induration, scaling, and erythema. The participants psoriasis is assessed as 5-point scale as follows: cleared (0), minimal (1), mild (2), moderate (3), or severe (4); higher score indicates worse disease. The	Week 12

Cleared (0) and PGA Score of Mild or Better (<=2) at Week 12	table below shows the percentage of participants who achieved a PGA score of 0 and the percentage of participants who achieved a PGA score of 0, 1, or 2 at Week 12 in each treatment group.	
The Percentage of Participants Who Were PASI 50 Responders and the Percentage of Participants With a PASI Score of 0 at Week 12	The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). The table below shows the percentage of participants in each treatment group who were PASI 50 responders at Week 12 defined as participants who achieved a greater than or equal to (>=) 50% improvement in PASI score from baseline as well as the percentage of participants with a PASI score of 0.	Week 12
The Change From Baseline in Pediatric Quality of Life Inventory (PedsQL) Total Scale Score, Psychosocial Health Summary Score, and Physical Health Summary Score at Week 12	The PedsQL is a general health-related quality of life measure developed for use in children and adolescent populations. The Generic Core Scale contains 23 items and is comprised of 4 domains: physical, social, emotional, and school functioning. Each domain can be scored independently. Additionally, a Psychosocial Health and Physical Health Summary Score can be calculated as well as a total score. The measure distinguishes between healthy children and children with acute and chronic health conditions and disease severity within a chronic health condition. The measure is applicable for healthy school and community populations, as well as with pediatric populations with acute and chronic health conditions and has versions for both parent and teen report. Scores range from 0 to 100, and higher scores indicate better health related quality of life.	Week 12

The Percentage of Participants With CDLQI Scores of 0 or 1 at Week 12 for Randomized Participants With a Baseline CDLQI Score > 1		Week 12

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Janssen Research & Development, LLC

Collaborators

No information provided

Investigators

- Study Director: Janssen Research & Development, LLC Clinical Trial, Janssen Research & Development, LLC

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2010-03-18

First Submitted that Met QC Criteria
2010-03-18

First Posted (Estimated)
2010-03-22

Results Reporting Dates

Results First Submitted
2014-12-10

Results First Submitted that Met QC Criteria
2014-12-10

Results First Posted (Estimated)
2014-12-18

Study Record Updates

Last Update Submitted that met QC Criteria
2015-01-16

Last Update Posted (Estimated)
2015-01-29

Last Verified
2015-01

More Information

Terms related to this study

Keywords Provided by Janssen Research & Development, LLC

Ustekinumab
Injection
CNTO 1275
Stelara
Pediatric psoriasis
Adolescents

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Dermatologic Agents
Ustekinumab

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full disclaimer (https://clinicaltrials.gov/about site/disclaimer) for details.

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Patient Preference of Taclonex Ointment to Taclonex Scalp Suspension in Adult Subjects With Psoriasis Vulgaris (PSTaclonex)

ClinicalTrials.gov ID NCT01707043

Sponsor Wake Forest University

Information provided by Wake Forest University Health Sciences (Wake Forest University) (Responsible Party)

Last Update Posted 2018 09 10

Study Details Tab

Study Overview

Brief Summary

This is an open label, investigator blinded, cross over, prospective, single center study of subjects with plaque psoriasis. Taclonex® (calcipotriene 0.005% and betamethasone dipropionate 0.064%)

Feedback

Ointment and Taclonex Scalp® (calcipotriene 0.005% and betamethasone dipropionate 0.064%) Topical Suspension will each be applied topically once daily.

The primary objective is to assess the patient preference for Taclonex® (calcipotriene 0.005% and betamethasone dipropionate 0.064%) Ointment compared to Taclonex Scalp® (calcipotriene 0.005% and betamethasone dipropionate 0.064%) Topical Suspension in the treatment of plaque psoriasis.

Detailed Description

- Following satisfaction of entry criteria, all subjects at the Baseline/Screening visit will be randomized 1:1 to receive either Taclonex® (calcipotriene 0.005% and betamethasone dipropionate 0.064%) Ointment or Taclonex Scalp® (calcipotriene 0.005% and betamethasone dipropionate 0.064%) Topical Suspension to use once daily for three days to affected areas of the body, excluding face and intertriginous areas. Subjects will be aware of which product they are using. Investigators will remain blinded.
- Subjects will be randomized to use either the ointment or the scalp suspension for the first three day treatment period, then cross over to use the other product for second three day treatment period.
- Each medication will be used within its FDA approved label for the treatment of plaque psoriasis in subjects aged 18 and older. Subjects may not treat areas of the face, axilla or groin in this study.
- At the Day 3 and Day 6 visits the subjects will complete a questionnaire about their psoriasis treatment preferences.
- Pregnancy tests will be done on females of childbearing potential at Baseline/Screening.
- Adverse events will be monitored at each visit.

Official Title

Patient Preference of Taclonex Ointment to Taclonex Scalp Suspension in Adult Subjects With Psoriasis Vulgaris

Conditions

Plaque Psoriasis

Intervention / Treatment

- Drug: Taclonex

Other Study ID Numbers

- IRB00021361

Study Start

2012 10

Primary Completion (Actual)

2013 09

Study Completion (Actual)

2013 12

Enrollment (Actual)

20

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Daivobet (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Daivobet)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

North Carolina Locations

Winston-Salem, North Carolina, United States, 27157

Wake Forest University Health Sciences

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person s general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Subject is male or female, age 18 or older, in good health.
- Subject has plaque type psoriasis no history of or current pustular, erythrodermic or guttate psoriasis.
- Subject is capable of understanding and willing to provide a signed and dated written voluntary informed consent before any protocol specific procedures are performed.
- The percentage of overall body surface involvement is between 1 10% on the trunk or extremities and is amenable to topical treatment with less than 100g of topical medication per week.
- The subject has an investigator global assessment of mild to moderate plaque psoriasis (severity index between 2 and 3 on a 5 point scale).
- The subject is able to complete the study and comply with study instructions, including attending all study visits.
- If a female subject of childbearing potential, subject has a negative urine pregnancy test. Sexually active women of childbearing potential participating in the study must have been using a medically acceptable form of contraception (which includes barrier methods, oral contraception, injectable or implantable methods, or intrauterine devices) for at least three months prior to entry into the study. A woman of childbearing potential is defined as one who is biologically capable of becoming pregnant. Abstinence is considered an acceptable method of contraception.

Exclusion Criteria:

- Subject has used experimental drugs or devices at least one month prior to Baseline.
- Subject has used systemic corticosteroid, phototherapy, retinoids, methotrexate, cyclosporine, or other immunosuppressive agents or biologics therapy (ie, alefacept, etanercept, efalizumab) within four weeks of Baseline.
- Subject has used topical therapy, corticosteroid therapy, topical vitamin D analog or calcineurin inhibitors or , tazarotene within two weeks prior to the Baseline visit (eg, tar, anthralin, salicylic acid, lactic acid, urea preparations).
- Subject has other serious skin disorder or any chronic medical condition that is not well controlled.
- Subject has clinically relevant abnormal vital signs or findings on the physical examination.
- Subject has major illness within 30 days prior to the Baseline visit.
- Subject has history of any immunocompromising disease.
- Subject is pregnant or nursing. Pregnant and nursing females will not be allowed in the study, and females of childbearing potential will have a pregnancy test at Baseline.
- Subject has a skin condition or disease that may require concurrent therapy or may confound the evaluation; a history of hypersensitivity to any of the formulation components; or atopic dermatitis.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

Yes

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Other
Allocation : Randomized
Interventional Model : Crossover Assignment
Masking : Single (Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Active Comparator: Taclonex Ointment First All subjects will use Taclonex® (calcipotriene 0.005% and betamethasone dipropionate 0.064%) Ointment once daily for three days to affected areas, then switch to Taclonex Scalp® (calcipotriene 0.005% and betamethasone dipropionate 0.064%) Topical Suspension once daily to affected areas for three days	Drug: Taclonex • Subjects will be evaluated at baseline, Day 3 and Day 6 (or end of study). • Other Names: ◦ Taclonex® Ointment ◦ (calcipotriene 0.005% betamethasone dipropionate 0.064%) ◦ Taclonex Scalp® ◦ (calcipotriene 0.005% and betamethasone dipropionate 0.064%) ◦ Topical Suspension
Active Comparator: Taclonex Scalp Suspension first All subjects will use Taclonex Scalp® (calcipotriene 0.005% and betamethasone dipropionate 0.064%) Topical Suspension once daily to affected areas for three days, then switch to Taclonex® (calcipotriene 0.005%	Drug: Taclonex • Subjects will be evaluated at baseline, Day 3 and Day 6 (or end of study). • Other Names: ◦ Taclonex® Ointment ◦ (calcipotriene 0.005% betamethasone dipropionate 0.064%) ◦ Taclonex Scalp® ◦ (calcipotriene 0.005% and betamethasone dipropionate 0.064%) ◦ Topical Suspension

and betamethasone dipropionate 0.064%) Ointment once daily for three days to affected areas,	

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Subjective Subject Preference Survey for the First Treatment Session	Subjective Subject Preference Survey The Subjective Subject Preference Survey consist of 15 questions relating to patients preference of study drug. The survey includes questions such as how the medication feels to touch, how greasy it is, and time it takes to apply. The final question asks patients to rate the overall appeal of the vehicle. Questions are scored on a 7-point scale, where a score of 1 is extremely unpleasant, 4 is neutral, and a score of 7 is extremely appealing. Total preference score based on the Subjective Subject Preference Survey could range from 15-105.	3 days
Subjective Subject Preference Survey for the Second Treatment Session	Subjective Subject Preference Survey The Subjective Subject Preference Survey consist of 15 questions relating to patients preference of study drug. The survey includes questions such as how the medication feels to touch, how greasy it is, and time it takes to apply. The final question asks patients to rate the overall appeal of the vehicle. Questions are scored on a 7-point scale, where a score of 1 is extremely unpleasant, 4 is neutral, and a score of 7 is extremely appealing. Total preference score	3 days

	based on the Subjective Subject Preference Survey could range from 15-105.	

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Wake Forest University

Collaborators

- LEO Pharma

Investigators

- Principal Investigator: Steve R Feldman, M.D, Ph.D., Wake Forest University Health Sciences
- Principal Investigator: Alan B Fleischer, Jr, M.D., Wake Forest University Health Sciences
- Principal Investigator: Adele R Clark, PA C, Wake Forest University Health Sciences

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of

Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2012-10-09

First Submitted that Met QC Criteria
2012-10-12

First Posted (Estimated)
2012-10-15

Results Reporting Dates

Results First Submitted
2017-01-27

Results First Submitted that Met QC Criteria
2017-06-08

Results First Posted
2017-07-11

Study Record Updates

Last Update Submitted that met QC Criteria
2018-08-10

Last Update Posted
2018-09-10

Last Verified
2018-08

More Information

Terms related to this study

Keywords Provided by Wake Forest University Health Sciences (Wake Forest University)

plaque psoriasis

taclonex
crossover

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Anti Inflammatory Agents
Glucocorticoids
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Physiological Effects of Drugs
Anti Asthmatic Agents
Respiratory System Agents
Dermatologic Agents
Calcium Regulating Hormones and Agents
Calcium Channel Agonists
Membrane Transport Modulators
Molecular Mechanisms of Pharmacological Action
Vasoconstrictor Agents
Vitamins
Micronutrients
Bone Density Conservation Agents
Calcitriol
Betamethasone
Betamethasone Valerate
Betamethasone 17,21 dipropionate
Betamethasone benzoate
Calcipotriene
Betamethasone sodium phosphate

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

Yes

Studies A U.S. FDA-Regulated Device Product

No

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full disclaimer (https://clinicaltrials.gov/about site/disclaimer) for details.

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

Efficacy and Safety of Cyclosporine A Microemulsion in Maintenance Patients With Chronic Plaque Psoriasis

ClinicalTrials.gov ID **NCT00438360**

Sponsor Novartis Pharmaceuticals

Information provided by Novartis (Novartis Pharmaceuticals)

Last Update Posted 2011 08 09

Study Details Tab

Study Overview

Brief Summary

The study will evaluate the efficacy of cyclosporine at 2, 5 mg/kg/day bid (i.e. bis in a day), when administered twice a week compared to continuous administration, in patients with chronic plaque psoriasis.

Feedback

Official Title

A 24 week, Double blind, Randomized, Placebo controlled, Multicenter Study, to Evaluate the Effectiveness of Cyclosporine 2,5 mg/kg/Day Bid Twice a Week on Reducing Relapse Rate, in Maintenance Patients With Chronic Plaque Psoriasis

Conditions

Chronic Plaque Psoriasis

Intervention / Treatment

- Drug: Cyclosporine A microemulsion
- Drug: Placebo

Other Study ID Numbers

- COLO400CIT04

Study Start

2006 05

Primary Completion (Actual)

2007 11

Study Completion (Actual)

2007 11

Enrollment (Actual)

243

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease

(https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Cyclosporine (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Cyclosporine)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Italy

Bari, Italy
Novartis Investigative Site

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person s general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion criteria:

- Outpatients 18 years of age and older (max 65 years)
- Patients with chronic plaque psoriasis on disease remission (i.e. PASI ≤75% of PASI before cyclosporine continuous treatment course) entering a maintenance period
- Disease remission obtained with only cyclosporine as systemic therapy (maximum dose 5 mg/kg/day) for >8 weeks and <16 weeks
- PASI still <75% of PASI before cyclosporine continuous treatment course, at randomization to study treatment (8±2 days after disease remission)

Exclusion criteria:

- Abnormal renal function (creatinine ≥ 10% the upper limit of the reference range)
- Severe chronic degenerative diseases
- Severe uncontrolled hypertension
- Body weigh >110 kg
- Abnormal liver function
- Hyperkalemia or hyperuricemia
- Clinically significant impairment of hematopoietic and cardiovascular function
- Concomitant therapy with nephrotoxic medications
- Patients with malignancy or a history of malignancy
- Females of childbearing potential who are planning to become pregnant, who are pregnant and/or lactating, who are unwilling to use effective means of contraception
- Clinically significant uncontrolled bacterial, viral or fungal infection
- Evidence of drug and/or alcohol abuse

Ages Eligible for Study

18 Years to 65 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Active Comparator: Cyclosporine A Oral soft gelatin capsules of cyclosporine 10 mg, 25 mg, 50 mg or 100 mg administered twice a week for 24 weeks at the dosage of 5 mg/Kg/day in two daily administrations	Drug: Cyclosporine A microemulsion • Oral soft gelatin capsules of Cyclosporine 10 mg, 25 mg, 50 mg or 100 mg administered twice a week for 24 weeks at the dosage of 5 mg/Kg/day in two daily administrations • Other Names: ◦ Neoral
Placebo Comparator: Placebo Oral soft gelatin capsules of placebo matching cyclosporine administered twice a week for 24 weeks in two daily administrations	Drug: Placebo • Oral soft gelatin capsules of placebo matching cyclosporine administered twice a week for 24 weeks in two daily administrations

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With Relapse Rate (Success or Failure), as Assessed by Psoriasis Area and Severity Index (PASI) Score	PASI is an index used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 (best) to 72 (worst), with the highest score representing complete erythroderma of severest degree. Relapse is considered a worsening of psoriasis associated to a PASI score >75% of PASI score recorded before starting induction therapy with CsA (before study start). Each patient was considered as failure (relapse occurrence) if rate was >= 75%. In all the other cases the patient was considered as success (no relapse).	24 weeks

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Proportion of Participants With Clinical Relapse	Clinical relapse was defined as worsening of psoriasis associated with a Psoriasis Area and Severity Index (PASI) >75% of the PASI score assessed before the continuous treatment, or when the investigator or the patient judged it necessary to change the treatment.	24 weeks
Change From Baseline in Psoriasis Area and Severity Index (PASI) Score	PASI is an index used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 (best) to 72 (worst), with the highest score representing complete erythroderma of the severest degree.	baseline and week 24

Change From Baseline in Body Surface Area (BSA) Affected by Psoriasis	BSA is a measure of the percentage of body surface affected by psoriasis. Using the Mosteller Formula: BSA = BSA (m^2) = ([Height(in) x Weight(lbs)]/ 3131)½ . A covariance analysis was performed on all variables, with value assessed at visit 2 as covariate and center as effect. For each variable the changes versus the last available measures were computed	Baseline and week 24
Change From Baseline in Visual Analogue Scale (VAS) for Patient Self Assessment of Pruritus	Target lesion pruritus as measured by the Visual Analog Scale (VAS) from 0 to 100 mm at week 24 compared to baseline (with 0 being no pruritis and 100 being maximum pruritis).	Baseline and week 24
Safety / Tolerability Assessed by Adverse Events		24weeks

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Novartis Pharmaceuticals

Collaborators

No information provided

Investigators

- Study Director: Novartis, Novartis

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2007-02-21

First Submitted that Met QC Criteria
2007-02-21

First Posted (Estimated)
2007-02-22

Results Reporting Dates

Results First Submitted
2010-12-15

Results First Submitted that Met QC Criteria
2011-07-13

Results First Posted (Estimated)
2011-08-09

Study Record Updates

Last Update Submitted that met QC Criteria

2011-07-13

Last Update Posted (Estimated)

2011-08-09

Last Verified

2011-07

More Information

Terms related to this study

Keywords Provided by Novartis (Novartis Pharmaceuticals)

Cyclosporine, chronic plaque psoriasis, intermittent therapy

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action
Immunosuppressive Agents
Immunologic Factors
Physiological Effects of Drugs
Antifungal Agents
Anti Infective Agents
Dermatologic Agents
Antirheumatic Agents
Calcineurin Inhibitors
Cyclosporine
Cyclosporins

Study Documents

No study documents available

Record 1 of 1

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Read our full disclaimer (https://clinicaltrials.gov/about site/disclaimer) for details.

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

A Short-contact Plaque Test Study With Daivobet® Gel in Psoriasis Vulgaris

ClinicalTrials.gov ID **NCT01607853**

Sponsor LEO Pharma

Information provided by LEO Pharma (Responsible Party)

Last Update Posted 2015 04 14

Study Details Tab

Study Overview

Brief Summary

Feedback

The purpose of this study is to evaluate the anti psoriatic effect of Daivobet® gel applied then removed after 10 minutes (+/ 2 minutes), Daivobet® gel applied then removed after 20 minutes (+/ 2 minutes) compared with Daivobet® gel and Daivobet® gel vehicle applied for 24 hours (+/ 2 hours), using the psoriasis plaque test modified from the method developed by KJ Dumas and JR Scholtz.

Official Title

A Phase IIa Exploratory Study Evaluating the Anti psoriatic Effect of Daivobet® Gel Applied Then Removed After 10 Minutes, Daivobet® Gel Applied Then Removed After 20 Minutes, Daivobet® Gel Applied for 24 Hours and Daivobet® Gel Vehicle Applied for 24 Hours

Conditions

Psoriasis Vulgaris

Intervention / Treatment

- Drug: Daivobet® gel applied then removed after 10 minutes (+/ 2 minutes)
- Drug: Daivobet® gel applied then removed after 20 minutes (+/ 2 minutes)
- Drug: Daivobet® gel applied for 24 hours (+/ 2 hours)
- Drug: Daivobet® gel vehicle applied for 24 hours (+/ 2 hours)

Other Study ID Numbers

- LP0076 57
- 2012 001507 21 (EudraCT Number)

Study Start

2012 06

Primary Completion (Actual)

2012 10

Study Completion (Actual)

2012 10

Enrollment (Actual)

24

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Daivobet (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Daivobet)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

France

Nice, France, 06202
Centre de Pharmacologie Clinique
Appliquée à la Dermatologie (CPCAD)

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a persons general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

1. Following verbal and written information about the trial, the subject has to provide signed and dated informed consent before any study related activities are carried out.
2. Age 18 years or above.
3. Either sex.
4. All skin types.
5. Subjects with a diagnosis of psoriasis vulgaris with lesions located on arms, legs and/or trunk. The lesions must have a total size suitable for application of 4 different products.
6. Subjects with, in the opinion of the investigator, stable psoriasis based on Total Plaque Score evaluated at screening visit and at visit 2 (baseline).
7. Subjects with psoriasis lesions (plaques) assessed by a Total Clinical Score (sum of scores of erythema, scaling and infiltration) of 4 to 9 inclusive, but each individual item ≥ 1.
8. Subjects willing and able to follow all the study procedures and complete the whole study.
9. Subjects affiliated to a social security system.
10. Female subjects of childbearing potential using a reliable method of contraception for at least 1 month before the study start and during the course of the study (e.g., oral contraceptive pill, intrauterine device, contraceptive patches, implantable contraception, condoms) or females of non childbearing potential (i.e. postmenopausal (absence of menstrual bleeding for 2 years), hysterectomy, bilateral ovariectomy or tubal section/ligation).
11. Female with a negative urine pregnancy test (at screening visit).

Exclusion Criteria:

1. Females who are pregnant, of child bearing potential and who wish to become pregnant during the study, or who are breast feeding.
2. Systemic treatment with biological therapies (marketed or not marketed) with a possible effect on psoriasis vulgaris within 4 weeks (etanercept), 2 months (adalimumab, alefacept, infliximab), 4 months (ustekinumab) or 4 weeks/5 half lives (which ever is longer) for experimental biological products prior to randomisation and during the study.
3. Systemic treatments with all other therapies than biologicals, with a potential effect on psoriasis vulgaris (e.g., corticosteroids, retinoids, immunosuppressants) within the 4 week period prior to randomisation and during the study.
4. Use of phototherapy within the following time periods prior to randomisation and during the study:
    - PUVA or Grenz ray therapy (4 weeks),
    - UVB (2 weeks).
5. Subjects using one of the following topical drugs within 4 weeks prior to randomisation and during the study:

    Potent or very potent (WHO group III IV) corticosteroids.

6. Subjects using one of the following topical drugs for the treatment of psoriasis within 2 weeks prior to randomisation and during the study:
    - WHO group I II corticosteroids (except if used for treatment of scalp and/or facial psoriasis),
    - Topical retinoids,
    - Vitamin D analogues,
    - Topical immunomodulators (e.g. calcineurin inhibitors),
    - Anthracen derivatives,
    - Tar,
    - Salicylic acid.
7. Subjects using emollients on the target plaques within one week before randomisation and during the study.
8. Initiation of, or expected changes in concomitant medication that may affect psoriasis vulgaris (e.g., beta blockers, anti malaria drugs, lithium and ACE inhibitors) within 2 weeks prior to randomisation and during the study.
9. Subjects with current diagnosis of guttate, erythrodermic, exfoliative or pustular psoriasis.
10. Subjects with known/suspected disorders of calcium metabolism associated with hypercalcemia within the last 10 years, based on medical history.
11. Subjects with any of the following conditions present on the test area: viral (e.g. herpes or varicella) lesions of the skin, fungal and bacterial skin infections, parasitic infections and atrophic skin.
12. Subjects with skin manifestations in relation to syphilis or tuberculosis, rosacea, perioral dermatitis, acne vulgaris, atrophic skin, striae atrophicae, fragility of skin veins, icthyosis, acne rosacea, ulcers and wounds within the plaque test areas.
13. History of any severe disease or serious current condition (based on subject interview and/or results of screening physical examination) which, in the opinion of the investigator, would put the subject at risk by participating in the study or would interfere significantly with the evaluation of study results or the study course (e.g. cancer, severe cardiopathy, severe renal insufficiency, severe hepatic insufficiency).
14. Subjects who have received treatment with any non marketed drug substance (i.e., an agent which has not yet been made available for clinical use following registration) within the 4 week period prior to randomisation or longer, if the class of the substance requires a longer washout as defined above (e.g., biological treatments).
15. Subjects with current participation in any other interventional clinical trial, based on interview of the subject.
16. Subjects with known or suspected hypersensitivity to component(s) of the investigational products.
17. Subjects with any concomitant medical or dermatological disorder(s) which might preclude accurate evaluation of the psoriasis.
18. Subjects foreseeing an intensive solar exposure during the study (UV radiation, etc.) or having been exposed within two weeks preceding the screening visit.
19. Subjects impossible to contact in case of emergency.
20. Subjects who are known or, in the opinion of the investigator, are unlikely to comply with the Clinical Study Protocol (e.g. alcoholism, drug dependency or psychotic state).

21. Subjects who are in an exclusion period in the National Biomedical Research Register of the French Ministry of Health at randomisation.
22. Subjects under guardianship, hospitalized in a public or private institution, for a reason other than the research or subject deprived of freedom.
23. Subjects previously randomised in this trial.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Allocation : Randomized
Interventional Model : Single Group Assignment
Masking : Single (Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Daivobet® gel	Drug: Daivobet® gel applied then removed after 10 minutes (+/- 2 minutes) • Once daily application, 3 weeks Drug: Daivobet® gel applied then removed after 20 minutes (+/- 2 minutes) • Once daily application, 3 weeks Drug: Daivobet® gel applied for 24 hours (+/- 2 hours) • Once daily application, 3 weeks Drug: Daivobet® gel vehicle applied for 24 hours (+/- 2 hours) • Once daily application, 3 weeks

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change in Total Clinical Score From Baseline to Day 22	Investigator s rating of the clinical appearance of a psoriatic lesion. Maximum score is 9 (most severe); minimum score is 0 (least severe). The single items erythema, scaling, and infiltration (maximum score 3 each) are summed to obtain the Total Clincal Score	baseline to day 22

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change in Total Clinical Score at Day 4 Compared to Baseline	Investigator s rating of the clinical appearance of a psoriatic lesion. Maximum score is 9 (most severe); minimum score is 0 (least severe). The single items erythema, scaling, and infiltration (maximum score 3 each) are summed to obtain the Total Clinical Score.	Baseline to day 4
Change in Total Clinical Score at Day 8 Compared to Baseline	Investigator s rating of the clinical appearance of a psoriatic lesion. Maximum score is 9 (most severe); minimum score is 0 (least severe). The single items erythema, scaling, and infiltration (maximum score 3 each) are summed to obtain the Total Clinical Score.	Baseline to day 8
Change in Total Clinical Score at Day 11 Compared to Baseline	Investigator s rating of the clinical appearance of a psoriatic lesion. Maximum score is 9 (most severe); minimum score is 0 (least severe). The single items erythema, scaling, and infiltration (maximum score 3 each) are summed to obtain the Total Clinical Score.	Baseline to day 11
Change in Total Clinical Score at Day 15 Compared to Baseline	Investigator s rating of the clinical appearance of a psoriatic lesion. Maximum score is 9 (most severe); minimum score is 0 (least severe). The single items erythema, scaling, and infiltration (maximum score 3 each) are summed to obtain the Total Clinial Score.	Baseline to day 15
Change in Total Clinical Score at Day 18 Compared to Baseline	Investigator s rating of the clinical appearance of a psoriatic lesion. Maximum score is 9 (most severe); minimum score is 0 (least severe). The single items erythema, scaling, and infiltration (maximum score 3 each) are summed to obtain the Total Clinical Score.	Baseline to day 18

Change From Baseline in Erythema at Day 4.	Investigator s rating of the clinical appearance of erythema. Maximum score is 3 (most severe); minimum score is 0 (absent).	Baseline to day 4
Change From Baseline in Erythema at Day 8.	Investigator s rating of the clinical appearance of erythema. Maximum score is 3 (most severe); minimum score is 0 (absent).	Baseline to day 8
Change From Baseline in Erythema at Day 11	Investigator s rating of the clinical appearance of erythema. Maximum score is 3 (most severe); minimum score is 0 (absent).	Baseline to day 11
Change From Baseline in Erythema at Day 15	Investigator s rating of the clinical appearance of erythema. Maximum score is 3 (most severe); minimum score is 0 (absent).	Baseline to day 15
Change From Baseline in Erythema at Day 18	Investigator s rating of the clinical appearance of erythema. Maximum score is 3 (most severe); minimum score is 0 (absent).	Baseline to day 18
Change From Baseline in Erythema at Day 22	Investigator s rating of the clinical appearance of erythema. Maximum score is 3 (most severe); minimum score is 0 (absent).	Baseline to day 22
Change From Baseline in Infiltration at Day 4	Investigator s rating of the clinical appearance of infiltration. Maximum score is 3 (most severe); minimum score is 0 (absent).	Baseline to day 4
Change From Baseline in	Investigator s rating of the clinical appearance of infiltration. Maximum score is 3 (most severe); minimum score is 0 (absent).	Baseline to day 8

Infiltration at Day 8		
Change From Baseline in Infiltration at Day 11	Investigator s rating of the clinical appearance of infiltration. Maximum score is 3 (most severe); minimum score is 0 (absent).	Baseline to day 11
Change From Baseline in Infiltration at Day 15	Investigator s rating of the clinical appearance of infiltration. Maximum score is 3 (most severe); minimum score is 0 (absent).	Baseline to day 15
Change From Baseline in Infiltration at Day 18	Investigator s rating of the clinical appearance of infiltration. Maximum score is 3 (most severe); minimum score is 0 (absent).	Baseline to day 18
Change From Baseline in Infiltration at Day 22	Investigator s rating of the clinical appearance of infiltration. Maximum score is 3 (most severe); minimum score is 0 (absent).	Baseline to day 22
Change From Baseline in Scaling at Day 4	Investigator s rating of the clinical appearance of scaling. Maximum score is 3 (most severe); minimum score is 0 (absent).	Baseline to day 4
Change From Baseline in Scaling at Day 8	Investigator s rating of the clinical appearance of scaling. Maximum score is 3 (most severe); minimum score is 0 (absent).	Baseline to day 8
Change From Baseline in Scaling at Day 11	Investigator s rating of the clinical appearance of scaling. Maximum score is 3 (most severe); minimum score is 0 (absent).	Baseline to day 11

Change From Baseline in Scaling at Day 15	Investigator s rating of the clinical appearance of scaling. Maximum score is 3 (most severe); minimum score is 0 (absent).	Baseline to day 15
Change From Baseline in Scaling at Day 18	Investigator s rating of the clinical appearance of scaling. Maximum score is 3 (most severe); minimum score is 0 (absent).	Baseline to day 18
Change From Baseline in Scaling at Day 22	Investigator s rating of the clinical appearance of scaling. Maximum score is 3 (most severe); minimum score is 0 (absent).	Baseline to day 22
Change in Lesion Thickness Measured by Ultrasound From Baseline to Day 22.		Baseline to day 22
Change in Skin Thickness - Echo-poor Band - Measured by Ultrasound From Baseline to Day 22		Baseline to day 22

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

LEO Pharma

Collaborators

No information provided

Investigators

- Principal Investigator: Catherine Queille Roussel, MD, Centre de Pharmacologie Clinique Appliquée à la Dermatologie (CPCAD), Hôpital lArchet 2, 151 route Saint Antoine de Ginestière 06202 Nice Cedex 3, France

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2012-05-23

First Submitted that Met QC Criteria
2012-05-25

First Posted (Estimated)
2012-05-30

Results Reporting Dates

Results First Submitted
2013-11-04

Results First Submitted that Met QC Criteria
2013-11-04

Results First Posted (Estimated)
2013-12-24

Study Record Updates

Last Update Submitted that met QC Criteria
2015-03-25

Last Update Posted (Estimated)
2015-04-14

Last Verified
2015-03

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Anti Inflammatory Agents
Glucocorticoids
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Physiological Effects of Drugs
Anti Asthmatic Agents
Respiratory System Agents
Calcium Regulating Hormones and Agents
Calcium Channel Agonists
Membrane Transport Modulators

Molecular Mechanisms of Pharmacological Action
Vasoconstrictor Agents
Vitamins
Micronutrients
Bone Density Conservation Agents
Calcitriol
Betamethasone

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

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Record 1 of 1

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

TERMINATED

In Amendment 1 of P05319 [NCT 00779675], the option to enroll into this study, was discontinued due to low numbers of participants with suboptimal response.

Dose Optimization of Infliximab in Moderate to Severe Plaque Psoriasis (Study P05315) (DOSE)

ClinicalTrials.gov ID **NCT00833053**

Sponsor Merck Sharp & Dohme LLC

Information provided by Merck Sharp & Dohme LLC (Responsible Party)

Last Update Posted 2017 04 12

Study Details Tab

Study Overview

Brief Summary

Feedback

Participants from an ongoing observational study (P05319) who have a limited (adequate but less than optimal) response to infliximab will be randomized to either increase the frequency of infliximab infusions from every 8 weeks to every 6 weeks, or to add weekly methotrexate to their current treatment plan. While receiving infliximab study treatment(s), patients in this study will attend regularly scheduled office visits for various clinical tests for safety and effectiveness evaluations.

Official Title

A Study of Dose Optimization of Infliximab in the Treatment of Moderate to Severe Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Infliximab
- Drug: Infliximab and methotrexate

Other Study ID Numbers

- P05315
- EUDRACT: 2008 000454 12

Study Start

2009 10

Primary Completion (Actual)

2011 04

Study Completion (Actual)

2011 04

Enrollment (Actual)

39

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Methotrexate (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Methotrexate)
Infliximab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Infliximab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

No location data

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person s general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Subjects must have a diagnosis of moderate to severe plaque type psoriasis and have had participated in Study P05319.
- Subjects must have demonstrated an adequate but suboptimal response to infliximab in Study P05319
- Subjects must be at least 18 years old
- Subjects must be candidates for phototherapy or systemic treatment for psoriasis.
- Subjects must not be pregnant and must meet contraceptive requirements
- Subjects must meet tuberculosis screening criteria
- Subjects must meet laboratory and medical history screening requirements

Exclusion Criteria:

- Subjects for whom infliximab or methotrexate is contraindicated or not recommended.
- Subjects already using certain investigational, biological, or immunosuppressive drugs
- Subjects with certain comorbid conditions
- Subjects who currently have or have a history of certain infections
- Subjects who have recently received live virus or bacterial vaccinations
- Subjects who are in a situation or have any condition that, in the opinion of the investigator, may interfere with optimal participation in the study.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: IFX q 6 weeks	Drug: Infliximab • Infliximab 5 mg/kg body weight intravenous infusion given every 6 weeks • Other Names: ◦ Remicade ◦ SCH 215596
Experimental: IFX + MTX	Drug: Infliximab and methotrexate • Infliximab 5 mg/kg body weight intravenous infusion (given every 8 weeks) plus methotrexate 7.5 mg orally (once weekly) • Other Names: ◦ Remicade ◦ SCH 215596

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Number of Participants With A Psoriasis Area and Sensitivity Index (PASI)-75 Response at Week 28	The Psoriasis Area and Sensitivity Index (PASI) is a measure of the average redness, thickness, and scaliness of psoriasis lesions. Each lesion is graded on a 0-4 scale, weighted by the area of involvement, with increasing scores indicating increasing severity. The PASI-75 response indicates the number of participants achieving a 75% reduction in PASI score compared to baseline.	Baseline, Week 28

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With A PASI-50 Response at Week 28	The PASI score is a measure of the average redness, thickness, and scaliness of psoriasis lesions. Each lesion is graded on a 0-4 scale, weighted by the area of involvement, with increasing scores indicating increasing severity.The PASI-50 response indicates the number of participants achieving a 50% reduction compared to baseline in PASI score.	Baseline, Week 28
Number of Participants With A PASI-90 Response at Week 28	The PASI score is a measure of the average redness, thickness, and scaliness of psoriasis lesions. Each lesion is graded on a 0-4 scale, weighted by the area of involvement, with increasing scores indicating increasing severity. The PASI-90 response indicates the number of participants achieving a 90% reduction compared to baseline in PASI score.	Baseline, Week 28
Number of Participants With A PASI-100 Response at Week 28	The PASI score is a measure of the average redness, thickness, and scaliness of psoriasis lesions. Each lesion is graded on a 0-4 scale, weighted by the area of involvement, with increasing scores indicating increasing severity. The PASI-100 response indicates the number of	Baseline, Week 28

	participants achieving a 100% reduction compared to baseline in PASI score.	
Change From Baseline in Mean Participant Raw PASI Scores at Week 28	The PASI score is a measure of the average redness, thickness, and scaliness of psoriasis lesions. Each lesion is graded on a 0-4 scale, weighted by the area of involvement, with increasing scores indicating increasing severity.	Baseline, Week 28
Dermatology Life Quality Index (DLQI) at Week 28	The DLQI is a 10-item questionnaire. Scores range from 0-10 with 0 indicating high quality of life and 10 indicating poor quality of life.	Week 28
Euro-Qol 5 Dimension (EQ-5D) Change From Baseline at Week 28	The EQ-5D is a descriptive system comprised of the following 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Participants are asked to indicate his/her health state by selecting the most appropriate statement in each of the 5 dimensions. This selection results in a 1-digit number expressing the level selected for that dimension. The digits for 5 dimensions can be combined in a 5-digit number describing the participant s health state. The numerals 1-5 have no arithmetic properties and should not be used as a cardinal score.	Baseline, Week 28

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Merck Sharp & Dohme LLC

Collaborators

No information provided

Investigators

No information provided

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

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Study Record Dates

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Study Registration Dates

First Submitted
2009-01-29

First Submitted that Met QC Criteria
2009-01-29

First Posted (Estimated)
2009-01-30

Results Reporting Dates

Results First Submitted
2012-03-15

Results First Submitted that Met QC Criteria
2012-06-19

Results First Posted (Estimated)
2012-07-26

Study Record Updates

Last Update Submitted that met QC Criteria
2017-03-15

Last Update Posted
2017-04-12

Last Verified
2017-03

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Abortifacient Agents, Nonsteroidal
Abortifacient Agents
Reproductive Control Agents
Physiological Effects of Drugs
Antimetabolites, Antineoplastic
Antimetabolites
Molecular Mechanisms of Pharmacological Action
Antineoplastic Agents
Dermatologic Agents
Enzyme Inhibitors
Folic Acid Antagonists
Immunosuppressive Agents
Immunologic Factors
Antirheumatic Agents
Nucleic Acid Synthesis Inhibitors
Tumor Necrosis Factor Inhibitors
Anti Inflammatory Agents
Gastrointestinal Agents

Infliximab

Methotrexate

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Yes

IPD Plan Description

http://www.merck.com/clinical trials/pdf/Merck%20Procedure%20on%20Clinical%20Trial%20Data%20Access%20Final_Updated%20July_9_2014.pdf

http://engagezone.msd.com/ds_documentation.php

Study Documents

No study documents available

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Record 1 of 1

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COMPLETED

Evaluation of the Efficacy and Tolerability of Clobetasol Propionate Foam Compared to Vehicle Foam

ClinicalTrials.gov ID **NCT00842153**

Sponsor Stiefel, a GSK Company

Information provided by GlaxoSmithKline (Stiefel, a GSK Company) (Responsible Party)

Last Update Posted 2017 10 09

Study Details Tab

Study Overview

Brief Summary

The purpose of the study is to compare the efficacy and safety of Clobetasol propionate to that of its Vehicle in the treatment of mild to moderate plaque type psoriasis.

Feedback

Detailed Description

The purpose of the study is to compare the efficacy and safety of Clobetasol propionate to that of its Vehicle in the treatment of mild to moderate plaque type psoriasis. This is a multi center, double blind, randomized, parallel designed study which consists of 2 weeks of treatment and a follow up visit 2 weeks later.

Official Title

A Study to Evaluate the Efficacy and Tolerability of Clobetasol Propionate vs. Vehicle in the Treatment of Mild to Moderate Plaque Type Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Clobetasol propionate foam
- Drug: Vehicle foam

Other Study ID Numbers

- OEF0701

Study Start

2007 11

Primary Completion (Actual)

2007 12

Study Completion (Actual)

2008 01

Enrollment (Actual)

58

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Clobetasol propionate (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Clobetasol+propionate)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

California Locations

Fremont, California, United States, 94538
Center for Dermatology, Cosmetic and Laser

Click to view interactive map

Kentucky Locations

Louisville, Kentucky, United States, 40202
Dermatology Specialists

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Outpatient, male or female of any race, and at least 12 years of age. Female subjects of childbearing potential must have a negative urine pregnancy test result at baseline and practice a reliable method of contraception throughout the study.
- Mild to moderate, plaque type psoriasis
- Target lesion on the trunk or extremities (excluding palms/soles, elbows, or knees) with a score of 2 or 3 for each of erythema, scaling and plaque thickness
- Able to understand the requirements of the study and sign Informed Consent/HIPAA Authorization Forms. Subjects under the legal age of consent in the state where the study is conducted must also have the written, informed consent of a parent or legal guardian.

Exclusion Criteria:

- Female subjects who are pregnant (positive urine pregnancy test) breast feeding or who are of childbearing potential and not practicing a reliable method of birth control
- Known allergy to clobetasol propionate or other topical corticosteroids; or to any component of the investigational formulations
- Subjects who have not complied with the proper wash out periods for prohibited medications
- Medical condition that in the opinion of the investigator, contraindicates the subject s participation in the clinical study
- Skin disease/disorder that might interfere with the study related diagnosis or evaluations
- Evidence of recent alcohol or drug abuse
- History of poor cooperation, non compliance with medical treatment or unreliability

Ages Eligible for Study

12 Years and older (Child, Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Clobetasol Propionate Foam Topical foam formulation that includes clobetasol propionate (Steroid)	Drug: Clobetasol propionate foam • Topical Clobetasol propionate foam • Other Names: ◦ Olux-E
Placebo Comparator: Vehicle Foam Vehicle foam is the same as the clobetasol propionate foam except it does not include the active drug.	Drug: Vehicle foam • Vehicle foam does not include the active drug.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With a Target Lesion Global Improvement (TLGI) Score of 0, 1, or 2 at Weeks 1, 2, and 4	The investigator assessed the TLGI of participants relative to their initial Baseline condition based on a 7-point scale: 0=completely cleared, possible residual discoloration; 1=almost cleared, 90% improvement, very significant clearance with only traces of disease remaining; 2=marked improvement, approximately 75%, with some disease remaining; 3=moderate improvement, approximately 50%; 4=mild improvement, approximately 25%, significant disease remains; 5=no change, no detectable improvement; 6=excerbation, worsening of signs and symptoms of disease.	Weeks 1, 2, and 4

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With a TLGI Score of 0, 1, 2, or 3 at Weeks 1, 2, and 4	The investigator assessed the TLGI of participants relative to their initial Baseline condition based on a 7-point scale: 0=completely cleared, possible residual discoloration; 1=almost cleared, 90% improvement, very significant clearance with only traces of disease remaining; 2=marked improvement, approximately 75%, with some disease remaining; 3=moderate improvement, approximately 50%; 4=mild improvement, approximately 25%, significant disease remains; 5=no change, no detectable improvement; 6=excerbation, worsening of signs and symptoms of disease.	Weeks 1, 2, and 4

Number of Participants With a Pruritus (Overall) Score of 0 or 1 at Week 2	Participants assessed their level of pruritus (itching) over the previous 24-hour period using the following scale: 0=no itching; 1=minimal, very rarely aware of localized itching, present when relaxing and lasted for very short time; 2=mild, aware of itching at times, present when relaxing, not present when focused on other activities; 3=moderate, often aware of itching, annoying, sometimes disturbed sleep and daytime activities; and 4=severe, constant itching, distressing, frequent sleep disturbance, interfered with activities.	Week 2
Number of Participants With an Erythema Score of 0 or 1 at Week 2	The investigator individually graded the severity of erythema (redness of skin) in participants as: 0=hyperpigmentation, pigmented macules (flat, distinct, colored area of skin), diffuse faint pink or red coloration; 1=no evidence of erythema, hyperpigmentation present; 2=faint erythema; 3=light red coloration; 4=moderate red coloration; and 5=bright red coloration.	Week 2
Number of Participants With a Scaling Score of 0 or 1 at Week 2	The investigator individually graded the severity of scaling in participants as: 0=no scaling; 1=no evidence of scaling; 2=minimal, occasional fine scale over less than 5% of the lesion; 3=mild, fine scales predominate; 4=moderate, coarse scales predominate; and 5=marked, thick nontenacious scales predominate.	Week 2
Number of Participants With a Plaque Thickness Score of 0 or 1 at Week 2	The investigator individually graded the severity of plaque thickness in participants as: 0=no elevation over normal skin; 1=possible but difficult to ascertain whether there is a slight elevation above normal skin; 2=slight but definite elevation, typically edges are indistinct or sloped; 3=moderate elevation with rough or sloped edges; 4=marked elevation typically with hard or	Week 2

	sharp edges; and 5=very marked elevation typically with hard, sharp edges.	
Number of Participants With a Score of 0 or 1 for Subject Global Assessment at Week 2	Participants assessed all treated areas using the Subject Global Assessment scale: 0=skin completely clear, possible residual hyperpigmentation; 1=psoriasis almost clear, patchy remnants of fine scaling present; 2=psoriasis mild, with small amount of psoriasis remaining (i.e., fine to coarse scales in some areas, definite redness, barely visible plaque thickness); 3=psoriasis moderate, between slight and definitely noticeable; 4=psoriasis very noticeable with redness, scaling, plaque thickness; 5=psoriasis severe with severe redness, thick scaling, and plaques.	Week 2
Mean Percent Change From Baseline to Week 2 in Pruritus (Target Lesion)	Participants assessed their level of pruritus (itching) for the target lesion using a 10 centimeter (cm) Visual Analogue Scale (VAS) with the left side anchored with "0=None" and the right side anchored with "10=Very Severe." A target lesion (>2 cm squared [cm^2]) was considered to be one on the trunk or extremities (excluding palms/soles, elbows, or knees). Percent change from Baseline was calculated as the value at Week 2 minus the value at Baseline (Week 0) divided by the Baseline (Week 0) value * 100.	Baseline (Week 0) and Week 2
Mean Percent Change From Baseline to Week 2 in Percent (%) of Body Surface Area (BSA) Affected	Percent change from Baseline was calculated as the value at Week 2 minus the value at Baseline (Week 0) divided by the Baseline (Week 0) value * 100. Data for this outcome measure were not collected; thus, no data were analyzed.	Baseline (Week 0) and Week 2

Number of Participants With a TLGI Score of 0, 1, or 2 at Week 1 and Week 4	The investigator assessed the TLGI of participants relative to their initial Baseline condition based on a 7-point scale: 0=completely cleared, possible residual discoloration; 1=almost cleared, 90% improvement, very significant clearance with only traces of disease remaining; 2=marked improvement, approximately 75%, with some disease remaining; 3=moderate improvement, approximately 50%; 4=mild improvement, approximately 25%, significant disease remains; 5=no change, no detectable improvement; 6=excerbation, worsening of signs and symptoms of disease.	Week 1 and Week 4
Number of Participants With a Pruritus (Overall) Score of 0 or 1 at Baseline and Week 4	Participants assessed their level of pruritus (itching) over the previous 24-hour period using the following scale: 0=no itching; 1=minimal, very rarely aware of localized itching, present when relaxing and lasted for very short time; 2=mild, aware of itching at times, present when relaxing, not present when focused on other activities; 3=moderate, often aware of itching, annoying, sometimes disturbed sleep and daytime activities; and 4=severe, constant itching, distressing, frequent sleep disturbance, interfered with activities.	Baseline (Week 0) and Week 4
Number of Participants With an Erythema Score of 0 or 1 at Baseline and Week 4	The investigator individually graded the severity of erythema (redness of skin) in participants as: 0=hyperpigmentation, pigmented macules (flat, distinct, colored area of skin), diffuse faint pink or red coloration; 1=no evidence of erythema, hyperpigmentation present; 2=faint erythema; 3=light red coloration; 4=moderate red coloration; and 5=bright red coloration.	Baseline (Week 0) and Week 4
Number of Participants	The investigator individually graded the severity of scaling in participants as: 0=no scaling; 1=no	Baseline (Week

With a Scaling Score of 0 or 1 at Baseline and Week 4	evidence of scaling; 2=minimal, occasional fine scale over less than 5% of the lesion; 3=mild, fine scales predominate; 4=moderate, coarse scales predominate; and 5=marked, thick nontenacious scales predominate.	0) and Week 4
Number of Participants With a Plaque Thickness Score of 0 or 1 at Baseline and Week 4	The investigator individually graded the severity of plaque thickness in participants as: 0=no elevation over normal skin; 1=possible but difficult to ascertain whether there is a slight elevation above normal skin; 2=slight but definite elevation, typically edges are indistinct or sloped; 3=moderate elevation with rough or sloped edges; 4=marked elevation typically with hard or sharp edges; and 5=very marked elevation typically with hard, sharp edges.	Baseline (Week 0) and Week 4
Number of Participants With a Score of 0 or 1 for Subject Global Assessment at Baseline and Week 4	Participants assessed all treated areas using the Subject Global Assessment scale: 0=skin completely clear, possible residual hyperpigmentation; 1=psoriasis almost clear, patchy remnants of fine scaling present; 2=psoriasis mild, with small amount of psoriasis remaining (i.e., fine to coarse scales in some areas, definite redness, barely visible plaque thickness); 3=psoriasis moderate, between slight and definitely noticeable; 4=psoriasis very noticeable with redness, scaling, plaque thickness; 5=psoriasis severe with severe redness, thick scaling, and plaques.	Baseline (Week 0) and Week 4
Mean Percent Change From Baseline to Week 4 in Pruritus (Target Lesion)	Participants assessed their level of pruritus (itching) for the target lesion using a 10 centimeter (cm) Visual Analogue Scale (VAS) with the left side anchored with "0=None" and the right side anchored with "10=Very Severe." A target lesion (>2 cm squared [cm^2]) was considered to be one on the trunk or extremities (excluding palms/soles, elbows, or knees). Percent change from Baseline was calculated as	Baseline (Week 0) and Week 4

	the value at Week 4 minus the value at Baseline (Week 0) divided by the Baseline (Week 0) value * 100.	
Mean Percent Change From Baseline to Week 4 in Percent (%) of Body Surface Area (BSA) Affected	Percent change from Baseline was calculated as the value at Week 4 minus the value at Baseline (Week 0) divided by the Baseline (Week 0) value * 100. Data for this outcome measure were not collected; thus, no data were analyzed.	Baseline (Week 0) and Week 4

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Stiefel, a GSK Company

Collaborators

- GlaxoSmithKline

Investigators

- Study Director: GSK Clinical Trials, GlaxoSmithKline

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2009-02-11

First Submitted that Met QC Criteria
2009-02-11

First Posted (Estimated)
2009-02-12

Results Reporting Dates

Results First Submitted
2011-12-21

Results First Submitted that Met QC Criteria
2011-12-21

Results First Posted (Estimated)
2012-01-30

Study Record Updates

Last Update Submitted that met QC Criteria

2017-10-05

Last Update Posted

2017-10-09

Last Verified

2017-10

More Information

Terms related to this study

Keywords Provided by GlaxoSmithKline (Stiefel, a GSK Company)

Psoriasis
Plaque Type Psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Anti Inflammatory Agents
Glucocorticoids
Hormones
Hormone Hormone Sub titute and Hormone Antagoni t
Physiological Effects of Drugs
Clobetasol

Study Documents

No study documents available

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Go to the classic website

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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

COMPLETED

PSUNRISE - Prospective Study Using Remicade in Psoriasis Patients With an Inadequate Response to Etanercept

ClinicalTrials.gov ID **NCT00527072**

Sponsor Centocor Ortho Biotech Services, L.L.C.

Information provided by Centocor Ortho Biotech Services, L.L.C. (Responsible Party)

Last Update Posted 2012 09 03

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to test the safety and effectiveness of infliximab in patients with plaque psoriasis who have been receiving the drug etanercept for treatment of their plaque psoriasis for at least four months, without enough improvement in their psoriasis symptoms.

Feedback

Detailed Description

The most common form of psoriasis is plaque type psoriasis, which is characterized by recurrent flaring of thickened, red, scaly patches of skin. Although psoriasis is usually not life threatening, these physical discomforts combined with the potential psychological effects of the disease may interfere with everyday activities and negatively impact an individual s quality of life. Many therapies are available for psoriasis; however, with limited effectiveness and significant toxicity. Infliximab is an antibody made in a laboratory. Antibodies are proteins that fight other substances in the body that may cause infections or diseases. A substance called "tumor necrosis factor" (TNF) naturally occurs in the body. TNF is related to the itchy patches of skin (or plaques) of psoriasis. Infliximab stops the TNF from working. Other studies have shown that stopping the TNF may reduce the plaques. To address the unmet medical need for effective chronic therapies, TNFalpha blockers have recently been used to treat patients with moderate to severe plaque psoriasis. Etanercept also works by stopping the TNF, but in a different way than infliximab. This multi center, open label study is designed to test whether or not patients with plaque psoriasis who have not responded well to etanercept treatment may benefit from treatment with infliximab. Key effectiveness measurements will include the time to onset of symptom improvement and health related quality of life. Safety will be assessed throughout the study. Two weeks after their last dose of etanercept, all eligible patients will receive open label 5 mg/kg infliximab infusions at Weeks 0, 2, 6, 14, and 22.

Official Title

A Multicenter, Open label Study to Assess the Efficacy and Safety of Infliximab (REMICADE®) Therapy in Patients With Plaque Psoriasis Who Had an Inadequate Response to Etanercept (ENBREL®)

Conditions

Psoriasis

Intervention / Treatment

- Biological: infliximab

Other Study ID Numbers

- CR014500
- C0168Z04 (Other Identifier) (OTHER: Centocor Ortho Biotech Services, L.L.C.)

Study Start

2007 07

Primary Completion (Actual)

2009 05

Study Completion (Actual)

2009 10

Enrollment (Actual)

217

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Psoriasis (https://medlineplus.gov/psoriasis.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Infliximab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Infliximab)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

No location data

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person s general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study basics/learn about studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Have plaque psoriasis despite at least 4 months of treatment with etanercept per current product labeling
- Have psoriatic target lesions that have a PGA score greater than 1 (minimal) at screening
- If receiving methotrexate at screening, must have received methotrexate for at least 3 months and at a stable dose of <= 25 mg/week for at least 4 weeks prior to screening
- If receiving cyclosporine at screening, must have received cyclosporine at a stable dose of <= 5 mg/kg daily for at least 4 weeks prior to screening.

Exclusion Criteria:

- Have already received infliximab or adalimumab
- Have shown a previous immediate hypersensitivity response, including anaphylaxis, to an immunoglobulin product
- Have a history of latent or active granulomatous infection, including tuberculosis, histoplasmosis, or coccidioidomycosis, prior to screening
- Have a concomitant diagnosis or any history of Congestive Heart Failure
- Are pregnant, nursing, or planning pregnancy
- Have used systemic corticosteroids within the 4 weeks prior to screening
- Have used topical corticosteroids or have initiated treatment with other topical therapies that could affect psoriasis or Psoriasis Area and Severity Index (PASI) evaluation (e.g., tar, anthralin, calcipotriene, tazarotene, methoxsalen) within 2 weeks prior to screening
- Have used new systemic agents/treatments, other than methotrexate, that can affect psoriasis including, but not limited to, immunosuppressants and/or psoralen plus ultraviolet A light (PUVA) within the 4 weeks prior to screening.

Ages Eligible for Study

18 Years to 75 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Non Randomized
Interventional Model : Single Group Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: 001 infliximabOpen-label 5 mg/kg infliximab infusions at Weeks 0, 2, 6, 14, and 22.	Biological: infliximab • Open-label 5 mg/kg infliximab infusions at Weeks 0, 2, 6, 14, and 22.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Patients Who Achieve a Physician Global Assessment (PGA) Score of Minimal (1) or Clear (0)	Patients who did not have a PGA score at Week 10 will be treated as not having achieved a PGA score of minimal (1) or clear (0) at Week 10. Specifically, treatment failures prior to Week 10 will be classified as not having a minimal (1) or clear (0).	Week 10

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Patients Achieved Psoriasis Area Activity Index (PASI) 50 Response at Week 10	A PASI 50 responder is defined as a patient who has achieved at least a 50% improvement in the overall PASI score from baseline. PASI is an index used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 to 72. A score less than 10 signifies a mixture of mild and moderate disease; a score greater than 10 but less than or equal to 30 signifies moderate disease; and a score greater than 30 signifies severe disease.	Week 10
Number of Patients Achieved Psoriasis Area Activity Index (PASI) 50 Response at Week 26		Week 26

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Centocor Ortho Biotech Services, L.L.C.

Collaborators

No information provided

Investigators