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Record 1 of 1

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COMPLETED

AN2728 Topical Ointment to Treat Mild-to-Moderate Plaque-Type Psoriasis

ClinicalTrials.gov ID NCT01300052

Sponsor Pfizer

Information provided by Pfizer (Responsible Party)

Last Update Posted 2017 04 17

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to determine whether AN2728 topical ointment is a safe and effective treatment for mild to moderate plaque type psoriasis.

Official Title

Feedback

A Multicenter, Randomized, Double Blind, 12 Week Study Of The Safety And Efficacy Of AN2728 Versus AN2728 Vehicle In The Treatment Of Patients With Mild To Moderate Plaque Type Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: AN2728 ointment, 2%
- Drug: Ointment Vehicle

Other Study ID Numbers

- AN2728 PSR 204
- C3291017 (Other Identifier) (OTHER: Alias Study Number)

Study Start (Actual)

2011 01 26

Primary Completion (Actual)

2011 06 06

Study Completion (Actual)

2011 06 06

Enrollment (Actual)

68

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

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

Connecticut Locations

New Haven, Connecticut, United States, 06511
The Savin Center

Kentucky Locations

Louisville, Kentucky, United States, 40202
Dermatology Specialists, PSC

Minnesota 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:

- Clinical diagnosis of stable mild to moderate plaque type psoriasis involving 2 35% of total body surface area (BSA) excluding face, scalp, and genitals
- Willingness and ability to apply study medication as directed, comply with study instructions, and commit to attending all study visits
- Women of childbearing potential must agree to use contraception for the entire study period

Exclusion Criteria:

- Any dermatological conditions that could interfere with clinical evaluations
- Concurrent or recent use of certain topical or systemic medications without a sufficient washout period
- Significant confounding conditions as assessed by study doctor
- Participated in any other trial of an investigational drug within 30 days or participation in a research study concurrent with this study
- Use of lithium or hydroxychloroquine containing products (e.g., Plaquenil)
- Use of a beta blocking medication (e.g., propranolol) if the dose has not been stabilized for at least 3 months
- Pregnancy or lactation

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: AN2728 ointment, 2% AN2728 ointment, 2%	Drug: AN2728 ointment, 2% • AN2728 ointment, 2%, applied twice daily for 12 weeks
Placebo Comparator: Ointment Vehicle Ointment Vehicle	Drug: Ointment Vehicle • Ointment Vehicle, applied twice daily for 12 weeks

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Percentage of Participants Who Achieved Success in Physicians Global Assessment (PGA) of Disease Severity at Day 84	PGA assessed severity of overall disease activity in participants. It was performed using a 6-point scale graded from 0 - 5, in which 0 = clear (no plaque elevation above normal skin level), 1 = almost clear (essentially flat with possible trace elevation), 2 = mild (slight but definite elevation of plaque above normal skin level), 3 = moderate (moderate elevation with rounded or sloped edges to plaque), 4 = severe (marked elevation with hard, sharp edges to plaque), 5 = very severe (very marked elevation with very hard, sharp edges to plaque). The success in PGA of disease severity was defined as a PGA score of 0 = clear or 1 = almost clear , with at least 2-grade improvement in PGA from Baseline to Day 84.	Day 84

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Who Achieved Success in Physicians Global Assessment (PGA) of Disease Severity at Days 14, 28, 42, 56, and 70	PGA assessed severity of overall disease activity in participants. It was performed using a 6-point scale graded from 0 - 5, in which 0 = clear (no plaque elevation above normal skin level), 1 = almost clear (essentially flat with possible trace elevation), 2 = mild (slight but definite elevation of plaque above normal skin level), 3 = moderate (moderate elevation with rounded or sloped edges to plaque), 4 = severe (marked elevation with hard, sharp edges to plaque), 5 = very severe (very marked elevation with very hard, sharp edges to plaque). The success in PGA of disease severity was defined as a PGA score of 0 = clear or 1 = almost clear , with at least 2-grade improvement in PGA from Baseline to Day 14, 28, 42, 56 and 70.	Day 14, Day 28, Day 42, Day 56, Day 70
Change From Baseline in	Percentage of the total body surface area (BSA) involved with psoriasis was measured. Change	Baseline (Day 1),

Percentage of Body Surface Area (%BSA) Involved With Psoriasis at Day 84	from Baseline (Day 1) in percentage of BSA at Day 84 was reported.	Day 84
Number of Participants With Treatment-Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs)	An AE was any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. An SAE was 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 are events between first dose of study drug and up to Day 84 that were absent before treatment or that worsened relative to pretreatment state. AEs included both SAE and non-SAE.	Baseline (Day 1) up to Day 84
Number of Treatment-Emergent Adverse Events (TEAEs) by Severity	An adverse event (AE) was any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. AEs were classified according to the severity in 3 categories a) mild =AEs does not interfere with participant s usual function b) moderate =AEs interfered to some extent with participant s usual function c) severe =AEs interfered significantly with participant s usual function and required systemic drug therapy. Treatment-emergent were events between first dose of study drug and up to Day 84 that were absent before treatment or that worsened relative to pretreatment state. In this outcome measure, number of mild, moderate and severe TEAEs were reported.	Baseline (Day 1) up to Day 84

Number of Participants With Local Tolerability Symptoms: Burning/Stinging	Local tolerability in participants was evaluated in terms of presence and absence of burning/stinging symptom and its severity in the areas of body where medication was applied. Burning/stinging symptoms were graded on a 4-point scale of 0 - 3 where 0 =none (no stinging/ burning), 1 =mild (slight warm, tingling sensation), 2 = moderate (definite warm; tingling/stinging sensation), 3 = severe (hot, tingling/stinging sensation that caused definite discomfort). Higher scores=Severe symptoms. In this outcome measure, number of participants with none, mild, moderate and severe burning/stinging symptoms were reported.	Baseline (Day 1) up to Day 84
Number of Participants With Local Tolerability Symptoms: Pruritus	Local tolerability was evaluated in participants in terms of presence and absence of pruritus symptom and its severity in the areas of body where medication was applied. Pruritus symptoms were graded on a 4-point scale of 0 - 3 where 0 =none (no pruritus), 1 =mild (occasional, slight itching/scratching), 2 = moderate (constant or intermittent itching/scratching which was not disturbing sleep), 3 = severe (bothersome itching/scratching which was disturbing sleep). Higher scores=Severe symptoms. In this outcome measure, number of participants with none, mild, moderate and severe pruritus symptoms were reported.	Baseline (Day 1) up to Day 84

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 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

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Study Registration Dates

First Submitted
2011-02-17

First Submitted that Met QC Criteria
2011-02-17

First Posted (Estimated)
2011-02-21

Results Reporting Dates

Results First Submitted
2017-01-12

Results First Submitted that Met QC Criteria
2017-01-12

Results First Posted
2017-03-07

Study Record Updates

Last Update Submitted that met QC Criteria
2017-03-17

Last Update Posted
2017-04-17

Last Verified
2017-03

More Information

Terms related to this study

Keywords Provided by Pfizer

psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

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COMPLETED

Safety and Efficacy Study of a Novel Ointment to Treat Plaque Type Psoriasis (AN2728PSR203)

ClinicalTrials.gov ID **NCT01029405**

Sponsor Pfizer

Information provided by Pfizer (Responsible Party)

Last Update Posted 2017 03 07

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to evaluate the safety and efficacy of AN2728 Ointment B, 2.0% and 0.5%, compared to Ointment Vehicle B, applied once or twice daily for 12 weeks, in the treatment of plaque type psoriasis

Feedback

Detailed Description

This is a multicenter, randomized, double blind, vehicle controlled, bilateral design. Patients will apply both test article AN2728 Ointment B (0.5% or 2%), and Ointment B Vehicle twice daily for 12 weeks. The assigned study medication will be applied to two comparable treatment targeted plaques identified at baseline. One test article will be applied to one plaque and the other test article to an anatomically distinct plaque. All efficacy evaluations will be measured from only the two plaques identified at the baseline visit.

Official Title

A Double Blind,Randomized, 12 Week, Bilateral Study of the Safety and Efficacy of AN2728 Ointment B, 2% and 0.5%, Versus Ointment B Vehicle in the Treatment of Patients With Plaque Type Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: AN2728
- Drug: Placebo

Other Study ID Numbers

- AN2728 PSR 203
- C3291016 (Other Identifier) (OTHER: Pfizer)

Study Start

2009 11

Primary Completion (Actual)

2010 05

Study Completion (Actual)

2010 06

Enrollment (Actual)

145

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

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.

Mexico

- Chihuahua, Mexico
- San Luis Potosí, Mexico

D.f. Locations

- Mexico City, D.f., Mexico

Jalisco Locations

- Zapopan, Jalisco, Mexico

Nuevo Leon 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:

- Male or female >18 years of age at time of enrollment
- Clinical diagnosis of stable plaque type psoriasis
- Two target plaques of similar severity meeting the following criteria:
    - 5 cm2 and ≤ 100 cm2, computed by multiplying the greatest diameter of the plaque by the diameter of the plaque perpendicular to the greatest diameter Bilaterally located (right/left) plaques on the arms or plaques located on the trunk. Plaques located on the trunk must be separated by at least 10 cm Overall target plaque severity score (OTPSS) of 2 4 (mild to moderate) with no more than a 1 point difference in the scores of the two target plaques
- Willing and able to apply study drug as directed, comply with study instructions and commit to all follow up visits
- Ability to understand, agree to and sign the study Informed Consent Form (ICF) prior to initiation of any protocol related procedures

Exclusion Criteria:

- Any dermatological conditions, disease state or physical condition that could interfere with clinical evaluations or might expose the patient to an unacceptable risk by study participation
- Any underlying disease(s) or other dermatological conditions that require the use of exclusionary topical or systemic therapy (see below)
- Clinically significant, abnormal Screening laboratory results (unless approved by the medical monitor)
- Known sensitivity to any of the components of the study medication
- Spontaneously improving or rapidly deteriorating psoriatic plaques or pustular/exfoliative, guttate, erythrodermic or other non plaque form of psoriasis
- Concomitant use of topical or systemic therapies that might alter the course of psoriasis
- Females of child bearing potential. Females must be post menopausal (based on FSH levels) or surgically sterile (hysterectomy or bilateral oophorectomy)
- Washout periods for exclusionary therapies:

Oral retinoids: 8 weeks Non retinoid systemic drugs that might alter the course of psoriasis: 4 weeks Psoralens with UV A (PUVA): 4 weeks Ultraviolet B (UVB) therapy: 4 weeks Topical drugs that might alter the course of psoriasis: 2 weeks Use of emollients/moisturizers on area(s) to be treated: 2 days prior to Baseline visit

- AIDS or AIDS related illness
- Concurrent participation in another drug or device research study or within 30 days prior to enrollment
- Use of lithium or hydroxychloroquine containing products (e.g., Plaquenil)

- Use of a beta blocking medication (e.g., Propranolol) if the dose has not been stabilized for at least 3 months
- Use of AN2728 in a previous clinical 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

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: 1. AN2728 Ointment B 2%, administered twice daily	Drug: AN2728 • Ointment B, 2% or 0.5% applied once or twice daily
Placebo Comparator: 2. AN2728 Ointment B Vehicle	Drug: Placebo • Ointment B Vehicle applied once or twice daily
Active Comparator: 3. AN2728 Ointment B 2%, administered once daily	Drug: AN2728 • Ointment B, 2% or 0.5% applied once or twice daily
Active Comparator: 4. AN2728 Ointment B 0.5%, administered twice daily	Drug: AN2728 • Ointment B, 2% or 0.5% applied once or twice daily
Active Comparator: 5. AN2728 Ointment B 0.5%, administered once daily	Drug: AN2728 • Ointment B, 2% or 0.5% applied once or twice daily

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With Greater Decrease In Overall Target Plaque Severity Score (OTPSS): Ointment (2% Twice Daily), Vehicle	OTPSS is a scale to assess plaque severity. Each target plaque was scored by the investigator on severity scale ranging from 0 (no plaque) to 8 (very severe plaque), where higher score indicates more severity of a plaque. In this outcome measure, percentage of participants with reduced OTPSS in ointment (2% twice daily) treated plaque versus (vs.) vehicle treated plaque and percentage of participants with reduced OTPSS in vehicle treated plaque versus ointment (2% twice daily) treated plaque respectively at Day 42 are reported.	Day 42

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With Greater Decrease In OTPSS: Ointment (0.5 % Once Daily, 0.5% Twice Daily and 2% Once Daily), Vehicle	OTPSS is a scale to assess plaque severity. Each target plaque was scored by the investigator on severity scale ranging from 0 (no plaque) to 8 (very severe plaque), where higher scores indicated more severity of a plaque. In this outcome measure, percentage of participants with reduced OTPSS in ointment (0.5 % once daily, 0.5% twice daily and 2% once daily) treated plaque versus vehicle treated plaque and percentage of participants with reduced OTPSS in vehicle treated plaque versus ointment (0.5 % once daily, 0.5% twice daily and 2% once daily) treated plaque respectively at Day 42 are reported.	Day 42

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

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Study Record Dates

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Study Registration Dates

First Submitted

2009-12-07

First Submitted that Met QC Criteria

2009-12-08

First Posted (Estimated)
2009-12-10

Results Reporting Dates

Results First Submitted
2017-01-12

Results First Submitted that Met QC Criteria
2017-01-12

Results First Posted
2017-03-07

Study Record Updates

Last Update Submitted that met QC Criteria
2017-01-12

Last Update Posted
2017-03-07

Last Verified
2017-01

More Information

Terms related to this study

Keywords Provided by Pfizer

Topical
Plaque type psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

Record 1 of 1

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COMPLETED

Phase 3 Study of M923 and Humira® in Subjects With Chronic Plaque-type Psoriasis

ClinicalTrials.gov ID NCT02581345

Sponsor Momenta Pharmaceuticals, Inc.

Information provided by Momenta Pharmaceuticals, Inc. (Responsible Party)

Last Update Posted 2018 10 17

Study Details Tab

Study Overview

Brief Summary

The purpose of the study is to evaluate efficacy, safety, and immunogenicity of a proposed adalimumab biosimilar (M923) and Humira in participants with moderate to severe chronic plaque type psoriasis.

Feedback

Official Title

A Phase 3 Randomized, Double blind, Multicenter Study to Evaluate Efficacy, Safety, and Immunogenicity of an Adalimumab Biosimilar (M923) and Humira® in Subjects With Moderate to Severe Chronic Plaque type Psoriasis

Conditions

Chronic Plaque Psoriasis Psoriasis

Intervention / Treatment

- Biological: M923
- Biological: Humira

Other Study ID Numbers

- 911401

Study Start

2015 09

Primary Completion (Actual)

2017 04 04

Study Completion (Actual)

2017 04 04

Enrollment (Actual)

572

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

California Locations

Beverly Hills, California, United States, 90211
Wallace Medical Group, Inc.

Encino, California, United States, 91436
Encino Research Center

La Mesa, California, United States, 91942
eStudySite

Oceanside, California, United States,



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. Must be able to understand and communicate with the investigator and comply with the requirements of the study
2. Chronic plaque type psoriasis diagnosed for at least 6 months before screening
3. Stable plaque psoriasis
4. History of receipt of or candidate for therapy.
5. Moderate to severe psoriasis at screening and baseline
6. Must be willing and able to self administer SC injections or have a caregiver available to administer injections
7. Male participants of childbearing potential must employ a highly effective contraceptive measure
8. Female participants must have a negative pregnancy test; are not planning to become pregnant; and must not be lactating. Female participants must also agree to employ a highly effective contraceptive measure.

Exclusion Criteria:

1. Forms of psoriasis other than chronic plaque type
2. Drug induced psoriasis.
3. Other skin conditions which would interfere with assessment of psoriasis
4. Medical conditions other than psoriasis for which systemic corticosteroids were used in the last year prior to screening
5. Other inflammatory conditions other than psoriasis or psoriatic arthritis
6. Prior use of systemic tumor necrosis factor (TNF) inhibitors, or 2 or more non TNF biologic therapies
7. Ongoing use of prohibited psoriasis treatments
8. Ongoing use of other non psoriasis prohibited treatments
9. All other prior non psoriasis concomitant treatments must be on a stable dose for at least 4 weeks
10. Laboratory abnormalities at screening deemed clinically significant by the investigator
11. Any condition or illness which in the opinion of the investigator or sponsor poses an unacceptable safety risk
12. History of latex allergy
13. History of or current signs or symptoms or diagnosis of a demyelinating disorder
14. History of or current Class III or IV New York Heart Association congestive heart failure
15. Signs, symptoms, or diagnosis of lymphoproliferative disorders, lymphoma, leukemia, myeloproliferative disorders, or multiple myeloma
16. Current malignancy or history of any malignancy except adequately treated or excised non metastatic basal cell or squamous cell cancer of the skin or cervical carcinoma in situ; no more than 3 lifetime basal cell and squamous cell carcinomas permitted
17. Chronic infections, recurrent infections; recent infection to be evaluated
18. History of or presence of human immunodeficiency virus (HIV), or Hepatitis B (HBV) or C virus (HCV)

19. History of active tuberculosis (TB) or untreated or inadequately treated latent TB.
20. Exposure to an investigational product ≤30 days prior to enrollment or participation in another clinical study during the course of this study
21. Participant is a family member or employee of the investigator or site staff or study team

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 : Factorial Assignment
Masking : Triple (Participant, Care Provider, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: M923 Participants assigned to receive M923	Biological: M923 • Recombinant human immunoglobulin G subclass 1 (IgG1) monoclonal antibody specific for human tumor necrosis factor-alpha (TNF-α) • Other Names: ◦ Adalimumab
Active Comparator: Humira Participants assigned to receive Humira	Biological: Humira • Recombinant human immunoglobulin G subclass 1 (IgG1) monoclonal antibody specific for human tumor necrosis factor-alpha (TNF-α) • Other Names: ◦ Adalimumab
Other: M923 and Humira Participants assigned to receive M923 and Humira	Biological: M923 • Recombinant human immunoglobulin G subclass 1 (IgG1) monoclonal antibody specific for human tumor necrosis factor-alpha (TNF-α) • Other Names: ◦ Adalimumab Biological: Humira • Recombinant human immunoglobulin G subclass 1 (IgG1) monoclonal antibody specific for human tumor necrosis factor-alpha (TNF-α) • Other Names:

	◦ Adalimumab

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Who Achieved a 75% Reduction in Psoriasis Area and Severity Index (PASI) (PASI 75) Scores at Week 16	The PASI combines assessments of the extent of body surface involvement in 4 anatomical regions (head, arms, trunk, and legs) and the severity of scaling, redness, and thickness in each region, yielding an overall score of 0 for no disease to 72 for the most severe disease. Each of the body areas was scored by itself, and then the 4 scores were combined into the final PASI score. Participants achieving PASI 75 are defined as having an improvement (reduction) of at least 75% in the Week 16 PASI score compared to the score at Baseline.	Baseline; Week 16

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With a Response of Clear or Almost Clear on the Static Physician Global Assessment (sPGA) at Week 16	The sPGA response rate was defined as the percentage of participants who had achieved a clear or almost clear response on the 6-point sPGA scale. The sPGA was the physician s determination of the participant s psoriasis lesions overall at a given time point. Overall lesions were categorized by descriptions for induration, erythema, and scaling. For the analysis of responses, the participant s psoriasis was assessed at a given time point on a 6-point scale on which 0 = cleared, 1 =	Week 16

	minimal, 2 = mild, 3 = moderate, 4 = severe, and 5 = very severe.	
Number of Participants Achieving PASI 50 Response at Week 16	The PASI combines assessments of the extent of body surface involvement in 4 anatomical regions (head, arms, trunk, and legs) and the severity of scaling, redness, and thickness in each region, yielding an overall score of 0 for no disease to 72 for the most severe disease. Each of the body areas was scored by itself, and then the 4 scores were combined into the final PASI score. Participants achieving PASI 50 are defined as having an improvement (reduction) of at least 50% compared to Baseline.	Baseline; Week 16
Number of Participants Achieving PASI 50 Response at Week 52 (Follow-Up Visit)	The PASI combines assessments of the extent of body surface involvement in 4 anatomical regions (head, arms, trunk, and legs) and the severity of scaling, redness, and thickness in each region, yielding an overall score of 0 for no disease to 72 for the most severe disease. Each of the body areas was scored by itself, and then the 4 scores were combined into the final PASI score. Participants achieving PASI 50 are defined as having an improvement (reduction) of at least 50% compared to Baseline.	Baseline; Week 52
Number of Participants Achieving PASI 75 Response at Week 52 (Follow-Up Visit)	The PASI combines assessments of the extent of body surface involvement in 4 anatomical regions (head, arms, trunk, and legs) and the severity of scaling, redness, and thickness in each region, yielding an overall score of 0 for no disease to 72 for the most severe	Baseline; Week 52

	disease. Each of the body areas was scored by itself, and then the 4 scores were combined into the final PASI score. Participants achieving PASI 75 are defined as having an improvement (reduction) of at least 75% compared to Baseline.	
Number of Participants Achieving PASI 90 Response at Week 16	The PASI combines assessments of the extent of body surface involvement in 4 anatomical regions (head, arms, trunk, and legs) and the severity of scaling, redness, and thickness in each region, yielding an overall score of 0 for no disease to 72 for the most severe disease. Each of the body areas was scored by itself, and then the 4 scores were combined into the final PASI score. Participants achieving PASI 90 are defined as having an improvement (reduction) of at least 90% compared to Baseline.	Baseline; Week 16
Number of Participants Achieving PASI 90 Response at Week 52 (Follow-Up Visit)	The PASI combines assessments of the extent of body surface involvement in 4 anatomical regions (head, arms, trunk, and legs) and the severity of scaling, redness, and thickness in each region, yielding an overall score of 0 for no disease to 72 for the most severe disease. Each of the body areas was scored by itself, and then the 4 scores were combined into the final PASI score. Participants achieving PASI 90 are defined as having an improvement (reduction) of at least 90% compared to Baseline.	Baseline; Week 52

Absolute PASI Score at Baseline	The PASI combines assessments of the extent of body surface involvement in 4 anatomical regions (head, arms, trunk, and legs) and the severity of scaling, redness, and thickness in each region, yielding an overall score of 0 for no disease to 72 for the most severe disease. Each of the body areas was scored by itself, and then the 4 scores were combined into the final PASI score.	Baseline
Absolute PASI Score at Week 16	The PASI combines assessments of the extent of body surface involvement in 4 anatomical regions (head, arms, trunk, and legs) and the severity of scaling, redness, and thickness in each region, yielding an overall score of 0 for no disease to 72 for the most severe disease. Each of the body areas was scored by itself, and then the 4 scores were combined into the final PASI score.	Week 16
Absolute PASI Score at Week 52 (Follow-Up Visit)	The PASI combines assessments of the extent of body surface involvement in 4 anatomical regions (head, arms, trunk, and legs) and the severity of scaling, redness, and thickness in each region, yielding an overall score of 0 for no disease to 72 for the most severe disease. Each of the body areas was scored by itself, and then the 4 scores were combined into the final PASI score.	Week 52
Percent Change From Baseline in PASI Score at Week 16	The PASI combines assessments of the extent of body surface involvement in 4 anatomical regions (head, arms, trunk,	Baseline; Week 16

	and legs) and the severity of scaling, redness, and thickness in each region, yielding an overall score of 0 for no disease to 72 for the most severe disease. Each of the body areas was scored by itself, and then the 4 scores were combined into the final PASI score. Percent change from Baseline was calculated as: (post-Baseline value - Baseline value) / (Baseline value) * 100.	
Percent Change From Baseline in PASI Score at Week 52 (Follow-Up Visit)	The PASI combines assessments of the extent of body surface involvement in 4 anatomical regions (head, arms, trunk, and legs) and the severity of scaling, redness, and thickness in each region, yielding an overall score of 0 for no disease to 72 for the most severe disease. Each of the body areas was scored by itself, and then the 4 scores were combined into the final PASI score. Percent change from Baseline was calculated as: (post-Baseline value - Baseline value) / (Baseline value) * 100.	Baseline; Week 52
Health-Related Quality of Life During Treatment: Dermatology Life Quality Index (DLQI) Score at Baseline	The DLQI score was calculated by summing the individual scores of each question at a given time point, resulting in a maximum score of 30 and a minimum score of 0. The higher the score, the more quality of life is impaired. For the analysis of responses, the participant s results were assessed on a scoring scale on which 3 = very much or yes (applicable to question 7 only), 2 = a lot, 1 = a little, 0 = not at all or not relevant. Interpretation of DLQI scoring can be taken as 0 - 1 = no effect	Baseline

	at all on participant s life, 2 - 5 = small effect on participant s life, 6 - 10 = moderate effect on participant s life, 11 - 20 = very large effect on participant s life, and 21 - 30 = extremely large effect on participant s life.	
Health-Related Quality of Life During Treatment: DLQI Score at Week 16	The DLQI score was calculated by summing the individual scores of each question at a given time point, resulting in a maximum score of 30 and a minimum score of 0. The higher the score, the more quality of life is impaired. For the analysis of responses, the participant s results were assessed on a scoring scale on which 3 = very much or yes (applicable to question 7 only), 2 = a lot, 1 = a little, 0 = not at all or not relevant. Interpretation of DLQI scoring can be taken as 0 - 1 = no effect at all on participant s life, 2 - 5 = small effect on participant s life, 6 - 10 = moderate effect on participant s life, 11 - 20 = very large effect on participant s life, and 21 - 30 = extremely large effect on participant s life.	Week 16
Health-Related Quality of Life During Treatment: DLQI Score at Week 48 (Completion/Termination Visit)	The DLQI score was calculated by summing the individual scores of each question at a given time point, resulting in a maximum score of 30 and a minimum score of 0. The higher the score, the more quality of life is impaired. For the analysis of responses, the participant s results were assessed on a scoring scale on which 3 = very much or yes (applicable to question 7 only), 2 = a lot, 1 = a little, 0 = not at all or not relevant. Interpretation of DLQI scoring can be taken as 0 - 1 = no effect	Week 48

	at all on participant s life, 2 - 5 = small effect on participant s life, 6 - 10 = moderate effect on participant s life, 11 - 20 = very large effect on participant s life, and 21 - 30 = extremely large effect on participant s life.	
Health-Related Quality of Life During Treatment: EuroQoL 5-Dimension Health Status Questionnaire (EQ-5D-5L) at Baseline	The EQ-5D-5L health score was measured on a Visual Analog Scale (VAS) anchored by 0 = "worst health you can imagine" and 100 = "best health you can imagine". Baseline was defined as the last scheduled observation prior to dosing, typically Day 1, predose.	Baseline
Health-Related Quality of Life During Treatment: EQ-5D-5L at Week 16	The EQ-5D-5L health score was measured on a Visual Analog Scale (VAS) anchored by 0 = "worst health you can imagine" and 100 = "best health you can imagine".	Week 16
Health-Related Quality of Life During Treatment: EQ-5D-5L at Week 48 (Completion/Termination Visit)	The EQ-5D-5L health score was measured on a Visual Analog Scale (VAS) anchored by 0 = "worst health you can imagine" and 100 = "best health you can imagine".	Week 48
Number of Participants With Clinically Meaningful Changes in Vital Signs	Vital signs included body temperature, respiratory rate, pulse rate, systolic and diastolic blood pressure, and weight. Clinically meaningful changes were classified as such by the Investigator and reported as adverse events.	Up to Week 52
Number of Participants With Clinically Significant Abnormalities in Laboratory Parameters at Baseline	Laboratory results included hematology [Hemoglobin, Hematocrit, Platelet count, Mean cell volume, White blood cell count (total leucocytes), Neutrophils absolute, Neutrophils, Lymphocytes absolute, Lymphocytes,	Baseline

	Monocytes, Eosinophils absolute, and Eosinophils], chemistry (Aspartate transaminase, Alanine transaminase, Gamma glutamyl transferase, Creatine kinase, C-reactive protein, Cholesterol, Triglycerides, Total protein, Potassium, Urea, Creatinine, Phosphate, Glucose, and Uric acid) and urinalysis [Specific Gravity] parameters. Laboratory results of a few hematology (Red Blood Cell Count and Monocytes absolute), chemistry (Alkaline Phosphatase, Total bilirubin, Sodium, Chloride, and Albumin), and urinalysis (pH) parameters were not assessed at Baseline and Week 16. Clinically meaningful changes were classified as such by the Investigator and reported as adverse events.	
Number of Participants With Clinically Significant Abnormalities in Laboratory Parameters at Week 16	Laboratory results included hematology [Hemoglobin, Hematocrit, Platelet count, Mean cell volume, White blood cell count (total leucocytes), Neutrophils absolute, Neutrophils, Lymphocytes absolute, Lymphocytes, Monocytes, Eosinophils absolute, and Eosinophils], chemistry (Aspartate transaminase, Alanine transaminase, Gamma glutamyl transferase, Creatine kinase, C-reactive protein, Cholesterol, Triglycerides, Total protein, Potassium, Urea, Creatinine, Phosphate, Glucose, and Uric acid) and urinalysis [Specific Gravity] parameters. Laboratory results of a few hematology (Red Blood Cell Count and Monocytes absolute), chemistry (Alkaline Phosphatase, Total bilirubin, Sodium, Chloride, and Albumin), and urinalysis (pH) parameters were not assessed at	Week 16

	Baseline and Week 16. Clinically meaningful changes were classified as such by the Investigator and reported as adverse events.	
Number of Participants With Clinically Significant Abnormalities in Laboratory Parameters at Week 48 (Completion/Termination Visit)	Laboratory results included hematology [Red Blood Cell Count, Hemoglobin, Hematocrit, Platelet count, Mean cell volume, White blood cell count (total leucocytes), Neutrophils absolute, Neutrophils, Lymphocytes absolute, Lymphocytes, Monocytes absolute, Monocytes, Eosinophils absolute, and Eosinophils], chemistry (Aspartate transaminase, Alanine transaminase, Alkaline Phosphatase, Gamma glutamyl transferase, Total bilirubin, Creatine kinase, C-reactive protein, Cholesterol, Triglycerides, Total protein, Sodium, Potassium, Chloride, Urea, Creatinine, Albumin, Phosphate, Glucose, and Uric acid) and urinalysis [pH and Specific Gravity] parameters. Clinically meaningful changes were classified as such by the Investigator and reported as adverse events.	Week 48
Number of Participants With Clinically Significant Abnormalities in Electrocardiogram Parameters at Baseline	Clinically significant abnormalities were classified as such by the Investigator and reported as adverse events.	Baseline
Number of Participants With Clinically Significant Abnormalities in Electrocardiogram Parameters at Week 16	Clinically significant abnormalities were classified as such by the Investigator and reported as adverse events.	Week 16

Number of Participants With Clinically Significant Abnormalities in Electrocardiogram Parameters at Week 48 (Completion/Termination Visit)	Clinically significant abnormalities were classified as such by the Investigator and reported as adverse events.	Week 48
Number of Participants With Treatment-emergent Adverse Events (TEAEs)	TEAEs are adverse events that occurred during or after study drug administration. For more details on adverse events please refer the safety section.	Up to Week 52
Pharmacokinetics: Serum Concentrations by Treatment	Serum samples were collected at Baseline (Week 0, perdose), approximately 1 week (peak) after IP administration (Weeks 8 and 16), and 2 weeks after dose administration as a trough sample collected prior to the next dose administration (Weeks 17, 21, 25, 29, 37, 41).	Baseline (Week 0), Week 8, 16, 17, 21, 25, 29, 37, and 41
Immunogenicity: Number of Participants With Anti-Drug Antibodies (ADA) at Baseline	The M923 confirmation assay was evaluated only if the EU Humira confirmation assay was negative. Overall Result: a participant was considered to be positive if a confirmed positive result was observed at any assay (including predose; if a participant had either a negative result in the screening assay or a positive result at screening followed by a negative result in all confirmation tiers, the overall result was negative. Overall Status: a participant was considered to have developed ADA or neutralizing ADAs if a confirmed positive result was observed at any time during the	Baseline (Week 0)

	treatment period inclusive of the predose results; the designation of negative required either a negative screening assay or a negative confirmation result at each sampling time. The same convention applied for the neutralizing assay results.	
Immunogenicity: Number of Participants With ADA at Week 16	The M923 confirmation assay was evaluated only if the EU Humira confirmation assay was negative. Overall Result: a participant was considered to be positive if a confirmed positive result was observed at any assay (including predose; if a participant had either a negative result in the screening assay or a positive result at screening followed by a negative result in all confirmation tiers, the overall result was negative. Overall Status: a participant was considered to have developed ADA or neutralizing ADAs if a confirmed positive result was observed at any time during the treatment period inclusive of the predose results; the designation of negative required either a negative screening assay or a negative confirmation result at each sampling time. The same convention applied for the neutralizing assay results.	Week 16
Immunogenicity: Number of Participants With ADA at Week 25	The M923 confirmation assay was evaluated only if the EU Humira confirmation assay was negative. Overall Result: a participant was considered to be positive if a confirmed positive result was observed at any assay (including predose; if a participant had either a negative result	Week 25

	in the screening assay or a positive result at screening followed by a negative result in all confirmation tiers, the overall result was negative. Overall Status: a participant was considered to have developed ADA or neutralizing ADAs if a confirmed positive result was observed at any time during the treatment period inclusive of the predose results; the designation of negative required either a negative screening assay or a negative confirmation result at each sampling time. The same convention applied for the neutralizing assay results.	
Immunogenicity: Number of Participants With ADA at Week 52 (Completion/Termination Visit)	The M923 confirmation assay was evaluated only if the EU Humira confirmation assay was negative. Overall Result: a participant was considered to be positive if a confirmed positive result was observed at any assay (including predose; if a participant had either a negative result in the screening assay or a positive result at screening followed by a negative result in all confirmation tiers, the overall result was negative. Overall Status: a participant was considered to have developed ADA or neutralizing ADAs if a confirmed positive result was observed at any time during the treatment period inclusive of the predose results; the designation of negative required either a negative screening assay or a negative confirmation result at each sampling time. The same convention applied for the neutralizing assay results.	Week 52

Immunogenicity: Number of Participants With ADA and nADA by Titer at Baseline	The M923 confirmation assay was evaluated only if the EU Humira confirmation assay was negative. Overall Result: a participant was considered to be positive if a confirmed positive result was observed at any assay (including predose); if a participant had either a negative result in the screening assay or a positive result at screening followed by a negative result in all confirmation tiers, the overall result was negative. Overall Status: a participant was considered to have developed ADA or neutralizing ADAs if a confirmed positive result was observed at any time during the treatment period inclusive of the predose results; the designation of negative required either a negative screening assay or a negative confirmation result at each sampling time. In confirmed positive samples, an assay was used to determine the relative titer of the ADA; a subsequent neutralizing antibodies assay was used to determine the presence of neutralizing antibodies.	Baseline (Week 0)
Immunogenicity: Number of Participants With ADA and nADA by Titer at Week 16	The M923 confirmation assay was evaluated only if the EU Humira confirmation assay was negative. Overall Result: a participant was considered to be positive if a confirmed positive result was observed at any assay (including predose); if a participant had either a negative result in the screening assay or a positive result at screening followed by a negative result in all confirmation tiers, the overall result was negative. Overall	Week 16

	Status: a participant was considered to have developed ADA or neutralizing ADAs if a confirmed positive result was observed at any time during the treatment period inclusive of the predose results; the designation of negative required either a negative screening assay or a negative confirmation result at each sampling time. In confirmed positive samples, an assay was used to determine the relative titer of the ADA; a subsequent neutralizing antibodies assay was used to determine the presence of neutralizing antibodies.	
Immunogenicity: Number of Participants With ADA and nADA by Titer at Week 25	The M923 confirmation assay was evaluated only if the EU Humira confirmation assay was negative. Overall Result: a participant was considered to be positive if a confirmed positive result was observed at any assay (including predose); if a participant had either a negative result in the screening assay or a positive result at screening followed by a negative result in all confirmation tiers, the overall result was negative. Overall Status: a participant was considered to have developed ADA or neutralizing ADAs if a confirmed positive result was observed at any time during the treatment period inclusive of the predose results; the designation of negative required either a negative screening assay or a negative confirmation result at each sampling time. In confirmed positive samples, an assay was used to determine the relative titer of the ADA; a subsequent neutralizing antibodies assay was used	Week 25

	to determine the presence of neutralizing antibodies.	
Immunogenicity: Number of Participants With ADA and nADA by Titer at Week 52 (Completion/Termination Visit)	The M923 confirmation assay was evaluated only if the EU Humira confirmation assay was negative. Overall Result: a participant was considered to be positive if a confirmed positive result was observed at any assay (including predose); if a participant had either a negative result in the screening assay or a positive result at screening followed by a negative result in all confirmation tiers, the overall result was negative. Overall Status: a participant was considered to have developed ADA or neutralizing ADAs if a confirmed positive result was observed at any time during the treatment period inclusive of the predose results; the designation of negative required either a negative screening assay or a negative confirmation result at each sampling time. In confirmed positive samples, an assay was used to determine the relative titer of the ADA; a subsequent neutralizing antibodies assay was used to determine the presence of neutralizing antibodies.	Week 52
Median Time to Seroconversion	Time to seroconversion (in days) was defined as the time to the observation of the first confirmed positive ADA response. Participants with confirmed positive ADA response at baseline (Week 0 predose) were excluded.	Up to Week 52

Collaborators and Investigators

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

Sponsor

Momenta Pharmaceuticals, Inc.

Collaborators

No information provided

Investigators

- Study Director: John Caminis, MD, Shire

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

2015-10-19

First Submitted that Met QC Criteria

2015-10-19

First Posted (Estimated)
2015-10-21

Results Reporting Dates

Results First Submitted
2018-05-18

Results First Submitted that Met QC Criteria
2018-09-10

Results First Posted
2018-09-12

Study Record Updates

Last Update Submitted that met QC Criteria
2018-10-15

Last Update Posted
2018-10-17

Last Verified
2018-10

More Information

Terms related to this study

Keywords Provided by Momenta Pharmaceuticals, Inc.

Moderate to severe chronic plaque psoriasis
Psoriasis

Additional Relevant MeSH Terms

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

Drug and device information, study documents, and helpful links

Study Documents

- Study Protocol (https://storage.googleapis.com/ctgov2 large docs/45/NCT02581345/Prot_000.pdf) [PDF, 0.79MB, 2016 08 04]
- Statistical Analysis Plan (https://storage.googleapis.com/ctgov2 large docs/45/NCT02581345/SAP_001.pdf) [PDF, 1.21MB, 2016 10 25]

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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

Non-interventional Study of Long-term Treatment of Psoriasis With Calcipotriol Plus Betamethasone in Gel Formulation

ClinicalTrials.gov ID NCT01707368

Sponsor LEO Pharma

Information provided by LEO Pharma (Responsible Party)

Last Update Posted 2018 09 24

Study Details Tab

Study Overview

Brief Summary

The purpose of this observational study is to document the course of disease and relapse management during treatment with Daivobet® Gel under consideration of patient s individual application habits under daily use conditions.

Feedback

Official Title

Course of Psoriasis During Long Term Treatment With Calcipotriol Plus Betamethasone in Gel Formulation

Conditions

Psoriasis Vulgaris Plaque Psoriasis

Intervention / Treatment

- Drug: Daivobet® Gel

Other Study ID Numbers

- DE Daivobet longterm NIS 2012

Study Start

2012 10

Primary Completion (Actual)

2014 05

Study Completion (Actual)

2014 07

Enrollment (Actual)

561

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: 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.

Germany

Niedersachsen Locations

Osnabrück, Niedersachsen, Germany, 49078
PD Dr. med. Rosenbach

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:

- Patients with light to moderate psoriasis vulgaris of trunk and extremities and treatment with Daivobet® Gel was planned anyway.
- Minimum of 3 years diagnosed psoriasis vulgaris.

Exclusion Criteria:

- Previous therapy with Daivobet® Gel
- Systemic therapy of psoriasis vulgaris
- Contraindications of Daivobet® Gel in the German package insert
- people that are incapable to give free consent

Study Population

Patients with Psoriasis vulgaris visiting their attending dermatologist in the primary care clinic

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

Cohorts and Interventions

Group/Cohort	Intervention/Treatment
all eligible patients Daivobet® Gel once daily on areas with plaque psoriasis, treatment duration up to 8 weeks for body skin areas except scalp (scalp up to 4 weeks), treatment may be repeated under medical surveillance.	Drug: Daivobet® Gel • Once daily on areas with plaque psoriasis, treatment duration up to 8 weeks for body skin areas except scalp (scalp up to 4 weeks), treatment may be repeated under medical surveillance.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Course of Disease and Relapse Management During Treatment With Daivobet® Gel Under Consideration of Patient s Individual Application Habits Under Daily Use Conditions.	Number of exacerbations and relapses during one year observation time	1 year

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
PGA (Physicians Global Assessment of Psoriasis Vulgaris Severity)	6--point verbal rating scale	Baseline
PGA (Physicians Global Assessment of Psoriasis Vulgaris Severity)	Assessment on 6-step scale from "no visible disease (0)" to "very severe disease (5)	1 year
Side Effects	Number of participants with serious and non-serious adverse drug reactions.	1 year

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: Thomas Rosenberg, PD Dr. med., private practise, D 49078 Osnabrück, 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
2012-10-12

First Submitted that Met QC Criteria
2012-10-12

First Posted (Estimated)
2012-10-16

Results Reporting Dates

Results First Submitted
2018-01-24

Results First Submitted that Met QC Criteria
2018-01-24

Results First Posted
2018-09-24

Study Record Updates

Last Update Submitted that met QC Criteria

2018-01-24

Last Update Posted

2018-09-24

Last Verified

2018-01

More Information

Terms related to this study

Keywords Provided by LEO Pharma

Psoriasis
Psoriasis vulgaris
Plaque Psoriasis
Daivobet® Gel
Germany

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

Record 1 of 1

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COMPLETED

A Clinical Study of Increased Dose of TA-650 in Patients With Psoriasis

ClinicalTrials.gov ID NCT01680159

Sponsor Mitsubishi Tanabe Pharma Corporation

Information provided by Mitsubishi Tanabe Pharma Corporation (Responsible Party)

Last Update Posted 2017 03 13

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to evaluate the efficacy, safety and pharmacokinetics of TA 650 at increased dose of 10 mg/kg every 8 weeks in patients with psoriasis in whom effect of the treatment was confirmed after the treatment with Remicade® at 5 mg/kg every 8 weeks but decreased thereafter.

Feedback

Detailed Description

- Patients with plaque psoriasis or psoriatic arthritis:
    1. Screening Period:

       TA 650 at 5 mg per kg body weight is administered on the day of TA 650 administration at the start (week 0) and week 8 (if efficacy is not judged as decreased or maintained at week 8 of the screening period) , respectively, by intravenous infusion slowly over at least 2 hours.
    2. Increased Dose Period:

       If efficacy is judged as decreased in the screening period, TA 650 at 10 mg per kg body weight is administered on the day of TA 650 administration at the start (week 0) and at every 8 weeks up to week 32 in the increased dose period , respecti ely, as one dose by intravenous infusion slowly over at least 2 hours.
- Patients with pustular psoriasis or psoriatic erythroderma:

TA 650 at 10 mg per kg body weight is administered on the day of TA 650 administration at the start (week 0) and at every 8 weeks up to week 32, respectively, as one dose by intravenous infusion slowly over at least 2 hours.

Conditions

Plaque Psoriasis | Psoriatic Arthritis | Pustular Psoriasis (Excluding a Localized) | Psoriatic Erythroderma

Intervention / Treatment

- Drug: TA 650

Other Study ID Numbers

- TA 650 24

Study Start

2012 07

Primary Completion (Actual)

2015 03

Study Completion (Actual)

2015 03

Enrollment (Actual)

51

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus Genetics (https://medlineplus.gov/genetics/) related topics: Psoriatic arthritis (https://medlineplus.gov/genetics/condition/psoriatic arthritis)

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: Pustular Psoriasis (https://rarediseases.info.nih.gov/diseases/12813/pustular psoriasis) Exfoliative Dermatitis (https://rarediseases.info.nih.gov/diseases/6393/exfoliative dermatitis) Spondylarthropathy (https://rarediseases.info.nih.gov/diseases/4971/spondylarthropathy)

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.

Japan

- **Chubu, Japan**
  Investigational site
- **Chugoku, Japan**
  Investigational site
- **Hokkaido, Japan**
  Investigational site
- **Kanto, Japan**
  Investigational site
- **Kinki, Japan**
  Investigational 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

Inclusion Criteria:

- Patients who have already been diagnosed as having plaque psoriasis, psoriatic arthritis, pustular psoriasis (excluding a localized), or psoriatic erythroderma.
- Patients in whom effect of the treatment was confirmed for a certain period after the start of administration of Remicade® at 5 mg/kg at every 8 weeks but decreased thereafter.

Exclusion Criteria:

- Patients who have guttate psoriasis.
- Patients who have drug induced psoriasis
- Patients who have previously used any other biological products than infliximab.
- Patients who have a concomitant diagnosis, or a history within 6 months prior to provisional enrollment, of serious infections that need hospitalization.
- Patients who have a concomitant diagnosis, or a history within 6 months prior to provisional enrollment, of opportunistic infections
- Female patients who are pregnant, breast feeding, or possibly pregnant.

Ages Eligible for Study

16 Years to 75 Years (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 : N/A
Interventional Model : Single Group Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: TA-650	Drug: TA-650

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Patients Achieving 75% Improvement in the Psoriasis Area and Severity Index (PASI) Score	The investigator or the subinvestigator examined the head, trunk, and upper and lower limbs, and assessed skin findings (erythema, induration, and scaling [scale]) at each of the regions and the extent of area affected. Total sores were calculated scores of the each regions. When the day of the assessment fell on a day on which study product was to be administered, the assessment was performed before the study product was administered. As a rule, the PASI score assessments for each patient were performed by the same investigator throughout the study, unless there	Weeks 0, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40 in Increased Dose Period

	was a special reason why this was not done (e.g., the investigator changed jobs). The number and percentage of patients achieving a 75% improvement in their PASI scores at each assessment time point.	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Psoriasis Area and Severity Index (PASI) Score	Score range is 0-72. Higher values represent a worse outcome. The investigator or the subinvestigator examined the head, trunk, and upper and lower limbs, and assessed skin findings (erythema, induration, and scaling [scale]) at each of the regions and the extent of area affected. Total sores were added scores of the each regions.	Weeks 0, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40 in Increased Dose Period
Percentage of Participants With Cleared and Minimal Skin Lesions of Physician Global Assessment (PGA) (Only for Patients With Plaque Psoriasis)	The investigator or the subinvestigator made a global assessment of skin lesions in terms of the degree of erythema, induration, and scaling (scale), using the following 6-point scale (0 to 5). When the day of the assessment fell on a day on which study product was to be administered, the assessment was performed before the study product was administered. As a rule, the PGA for each patient were performed by the same investigator or subinvestigator throughout the study, unless there was a special reason why this was not done (e.g., the investigator or the subinvestigator changed jobs). Outcome measure data table is reported percentage of participants with Cleared and Minimal skin lesions.	Weeks 0, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40 in Increased Dose Period

	0: Cleared, 1: Minimal, 2: Mild, 3: Moderate, 4: Marked, 5: Severe	
Visual Analog Scale (VAS) of Pain Assessment by Subjects (Only for Patients With Psoriatic Arthritis)	From 0 (best) to 100 (worst)	Weeks 0, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40 in Increased Dose Period
Assessment of Severity (Only for Patients With Pustular Psoriasis)	From 0 (best) to 17 (worst)	Weeks 0, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40 in Increased Dose Period

Collaborators and Investigators

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

Sponsor

Mitsubishi Tanabe Pharma Corporation

Collaborators

No information provided

Investigators

- Study Director: Hideshi Torii, MD, Social Insurance Central General Hospital
- Study Director: Kazuoki Kondo, MD, Mitsubihsi Tanabe Pharma Corporation

- Study Chair: Hidemi Nakagawa, MD, The Jikei University School of Medicine

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
2012-08-28

First Submitted that Met QC Criteria
2012-09-03

First Posted (Estimated)
2012-09-07

Results Reporting Dates

Results First Submitted
2016-11-09

Results First Submitted that Met QC Criteria
2017-01-23

Results First Posted

2017-03-13

Study Record Updates

Last Update Submitted that met QC Criteria
2017-01-23

Last Update Posted
2017-03-13

Last Verified
2016-11

More Information

Terms related to this study

Keywords Provided by Mitsubishi Tanabe Pharma Corporation

Infliximab
REMICADE
TA 650
psoriasis

Additional Relevant MeSH Terms

Arthritis
Joint Diseases
Musculoskeletal Diseases
Skin Diseases, Papulosquamous
Skin Diseases
Spondylarthropathies
Spondylarthritis
Spondylitis
Spinal Diseases
Bone Diseases
Dermatitis
Skin Diseases, Eczematous
Arthritis, Psoriatic
Psoriasis
Dermatitis, Exfoliative

Study Documents

No study documents available

ClinicalTrials.gov

Go to the classic website

Record 45 of 148

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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

An Observational Study of the Real Life Management of the Psoriasis Patients Treated With Enbrel According to the New Reimbursement Criteria (BEFLEX)

ClinicalTrials.gov ID: NCT01557283

Sponsor: Pfizer

Information provided by: Pfizer (Responsible Party)

Last Update Posted: 2014-06-30

Study Details Tab

Study Overview

Brief Summary

With the new reimbursement criteria, we want:

To describe the average treatment duration of patients with Enbrel expressed as a number of weeks/year.

To describe the number of patients who receive continuous treatment To describe the number of patients who receive intermittent treatment To describe the number of weeks offtreatment

Detailed Description

100 patients will be followed for at least 1 year

Official Title

An Observational Study of the Real Life Management of the Psoriasis Patients Treated With Enbrel According to the New Reimbursement Criteria - Beflex Study

Conditions

Plaque Psoriasis Patients

Intervention / Treatment

- Other: Enbrel treatment

Other Study ID Numbers

- B1801314
- BEFLEX

Study Start

2011-09

Primary Completion (Actual)

2013-06

Study Completion (Actual)

2013-06

Enrollment (Actual)

140

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: 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)

Feedback

Contacts and Locations

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

Belgium

Leuven, Belgium, 3000
Herestraat 49



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 restarts or is starting treatment with Enbrel for his/her psoriasis in alignment with reimbursement criteria
- Patients ≥18 year
- Evidence of a personally signed and dated informed consent document indicating that the subject (or a legally acceptable representative) has been informed of all pertinent aspects of the study.

Exclusion Criteria:

N/A

Study Population

All subjects enrolled should meet the usual prescribing criteria for Enbrel as per local reimbursement criteria and should be entered into the study at the investigator's discretion. It is requested to include patients in a consecutive manner as much as possible.

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
Plaque psoriasis patients	Other: Enbrel treatment
Plaque psoriasis patients treated with Enbrel after the approval of the new belgian reimbursement criteria	• Enbrel SC 50mg once weekly or 25mg twice weekly

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Weeks of Etanercept Treatment	Average duration of time in weeks for treatment with etanercept was reported.	Baseline up to end of study (90 weeks)

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Weeks of Off-Treatment	Total duration of time in weeks for which participants discontinued etanercept treatment was reported.	Baseline up to end of study (90 weeks)
Psoriasis Area and Severity Index (PASI) Score	Combined assessment of lesion severity and area affected into single score. Body was divided into 4 sections: head, arms, trunk, and legs. For each section, percent (%) area of skin involved was estimated: 0 = 0%, 1 = less than (<) 10%, 2 = 10 to <30%, 3 = 30 to <50%, 4 = 50 to <70%, 5= 70 to <90%, 6 = 90 to 100%. Severity was estimated by clinical signs: erythema, induration, desquamation; scale: 0 = none to 4 = maximum. Final PASI = sum of severity parameters for each section*area score*weight of section (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4); total possible score range: 0= no disease to 72= maximal disease.	Start and end of cycle 1, 2, 3
Percentage of Body Surface Area (BSA) Affected by Psoriasis	Percentage of body surface area affected by psoriasis was estimated using the palm method: one of the participant's palm to proximal interphalangeal and thumb = 1 percent (%) of total BSA. Regions of the body were assigned specific number of palms with percentage [Head and neck = 10% (10 palms), upper extremities = 20% (20 palms), Trunk (axillae and groin) = 30% (30 palms), lower extremities (buttocks) = 40% (40 palms)]. The total BSA affected was the summation of individual regions affected.	Start and end of cycle 1, 2, 3
Number of Participants With Reasons for Treatment Discontinuation	Number of participants who discontinued etanercept before completing the study was reported.	Baseline up to end of study (90 weeks)

Other Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants Who Received Continuous Treatment	Number of participants who were treated continuously with etanercept without any treatment discontinuation as per dermatologist's discretion was reported.	Baseline up to end of study (90 weeks)
Number of Participants Who Received Intermittent Treatment	Number of participants who received etanercept treatment in cycles of up to 24 weeks with at least 2 weeks of treatment discontinuation was reported.	Baseline up to end of study (90 weeks)

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

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Study Registration Dates

First Submitted
2011-09-30

First Submitted that Met QC Criteria
2012-03-15

First Posted (Estimated)
2012-03-19

Results Reporting Dates

Results First Submitted
2014-05-28

Results First Submitted that Met QC Criteria
2014-05-28

Results First Posted (Estimated)
2014-06-30

Study Record Updates

Last Update Submitted that met QC Criteria
2014-05-28

Last Update Posted (Estimated)
2014-06-30

Last Verified
2014-05

More Information

Terms related to this study

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 Pfizer

To obtain contact information for a study center near you, click here. (https://trialinformail.pfizer.com/pages/landing.aspx?StudyID=B1801314&StudyName=An%20Observational%20Study%20of%20the%20Real%20Life%20Management%20of%20the%20Psoriasis%20Patients%20Treated%20with%20Enbrel%20According%20to%20the%20New%20Reimbursement%20Cr)

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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 Safety, Tolerability, and Efficacy of Secukinumab in Subjects With Moderate to Severe Palmoplantar Psoriasis (GESTURE)

ClinicalTrials.gov ID NCT01806597

Sponsor Novartis Pharmaceuticals

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

Last Update Posted 2018 02 22

Study Details Tab

Study Overview

Brief Summary

Purpose of the study was to demonstrate the efficacy of secukinumab versus placebo on palmoplantar psoriasis and to assess the long term efficacy, safety and tolerability of secukinumab.

Feedback

Official Title

A Randomized, Double blind, Placebo controlled, Multicenter Study to Demonstrate the Efficacy at 16 Weeks of Secukinumab 150 and 300 mg s.c. and to Assess Safety, Tolerability and Long term Efficacy up to 132 Weeks in Subjects With Moderate to Severe Palmoplantar Psoriasis

Conditions

Moderate to Severe Palmoplantar Psoriasis

Intervention / Treatment

- Biological: secukinumab 150 mg
- Biological: secukinumab 300 mg
- Biological: Placebo

Other Study ID Numbers

- CAIN457A2312
- 2012 005412 25 (EudraCT Number)

Study Start (Actual)

2013 06 19

Primary Completion (Actual)

2016 11 02

Study Completion (Actual)

2016 11 02

Enrollment (Actual)

205

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: 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

Arizona Locations

Phoenix, Arizona, United States, 85032
Novartis Investigative Site

Indiana 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:

- Subjects with chronic, moderate to severe plaque type psoriasis for at least 6 months prior to randomization and significant involvement of the palms and soles at baseline, defined as palmoplantar Investigator s Global Assessment (ppIGA) score of ≥ 3 on a 5 point scale, as well as at least one skin plaque at baseline which is not in the palmoplantar area
- Candidates for systemic therapy, i.e. psoriasis inadequately controlled by topical treatment (including super potent topical corticosteroids) and/or phototherapy and/or previous systemic therapy

Exclusion Criteria:

- Forms of psoriasis other than chronic plaque type psoriasis (e.g., pustular psoriasis, palmoplantar pustulosis, acrodermatitis of Hallopeau, erythrodermic and guttate psoriasis)
- Drug induced psoriasis (e.g. new onset or current exacerbation from β blockers, calcium channel inhibitors or lithium)
- Ongoing use of prohibited treatments (e.g. topical or systemic corticosteroids (CS), UV therapy). Washout periods do apply.
- Prior exposure to secukinumab (AIN457) or any other biological drug directly targeting IL 17 or the IL 17 receptor
- Use of any investigational drugs within 4 weeks prior to study treatment initiation or within a period of 5 half lives of the investigational treatment, whichever is longer
- Active ongoing inflammatory diseases other than psoriasis that might confound the evaluation of the benefit of secukinumab therapy
- History of hypersensitivity to constituents of the study 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: secukinumab 150mg 201 subjects were randomized in a 1:1:1 ratio to secukinumab either 150 mg or 300 mg, or placebo. Subjects assigned to secukinumab 150 mg were dosed weekly for the first five weeks, then every four weeks up to and including Week 128. To maintain blinding, subjects received additional placebo injections at Weeks 17, 18 and 19. All doses of study treatment were administered by sub-cutaneous injections.	Biological: secukinumab 150 mg • Study treatment were provided in pre-filled syringes of secukinumab 150 mg in 1 mL. Each dosing consiseds of one secukinumab 150 mg s.c. injection plus one placebo secukinumab s.c. injection and took place once weekly during five weeks (at Baseline, Weeks 1, 2, 3 and 4), then once every four weeks starting at Week 8 until Week 128 inclusive. In order to maintain the blinding, patients also received two placebo injections at Weeks 17, 18 and 19. Patients self-administered study treatment under the supervision of site personnel when injections occur during study visits, or at home otherwise. • Other Names: ◦ AIN457 150 mg
Experimental: secukinumab 300 mg 201 subjects were randomized in a 1:1:1 ratio to secukinumab either 150 mg or 300 mg, or placebo. Subjects assigned to secukinumab 300 mg were dosed weekly for the first five weeks and	Biological: secukinumab 300 mg • Study treatment were provided in pre-filled syringes of secukinumab 150 mg in 1 mL. Each dosing consisted of two secukinumab 150 mg s.c. injections and took ke place once weekly during five weeks (at Baseline, Weeks 1, 2, 3 and 4), then once every four weeks starting at Week 8 until Week 128 inclusive. In order to maintain the blinding, patients also receives two placebo injections at Weeks 17, 18 and 19. Patients

then every four weeks up to and including Week 128. In order to maintain the blinding, subjects received additional placebo injections at Weeks 17, 18 and 19. All doses of study treatment were administered by sub-cutaneous injections.	self-administered study treatment under the supervision of site personnel when injections occur during study visits, or at home otherwise. • Other Names: ◦ AIN457 300 mg
Placebo Comparator: Placebo 201 subjects were randomized in a 1:1:1 ratio to secukinumab either 150 mg or 300 mg, or placebo. Subjects on placebo were dosed weekly for 5 weeks then once every 4 weeks. At Week 16, ppIGA responders continued to receive placebo weekly for 5 weeks starting at Week 16, then every 4 weeks up to and including Week 76 while ppIGA non-responders were randomized in a 1:1 ratio to secukinumab either 150 mg or 300mg weekly for 5 weeks, starting at Week 16, then every 4 weeks up to and including Week 128. At	Biological: Placebo • Placebo were provided in 1 mL pre-filled syringes. Each dosing consisted of two s.c. injections and took place once weekly during five weeks (at Baseline, Weeks 1, 2, 3 and 4), then at Week 8 and at Week 12. At Week 16, ppIGA responders continued on placebo with dosing at Weeks 16, 17, 18, 19 and 20, then once every four weeks from Week 24 until Week 76 inclusive. At Week 80, ppIGA responders ended their participation in the study while ppIGA non-responders were re-randomized, to receive 150 mg or 300 mg secukinumab once every four weeks starting at Week 80 until Week 128 inclusive. Patients self-administered study treatment under the supervision of site personnel when injections occur during study visits, or at home otherwise.

Week 80, subjects on placebo were either terminated their participation, if ppIGA responders, or randomized in a 1:1 ratio to secukinumab either 150 mg or 300 mg once every 4 weeks until Week 128 inclusive. All doses of study treatment were administered by sub-cutaneous injections.	

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentages of Participants With Palmoplantar Investigator Global Assessmnet (ppIGA) 0 or 1 Response After 16 Weeks of Treatment	palmoplantar Investigator s Global Assessment (ppIGA) response after 16 weeks of treatment. To be considered a ppIGA responder at Week 16, a subject must have ppIGA of 0 or 1 at Week 16 and a reduction of at least 2 points on the ppIGA scale from baseline.	Week 16

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Percentages of Participants With Palmoplantar Investigator Global Assessment (ppIGA) 0 or 1 Response - Treatment Period I	ppIGA: Palmoplantar Ivestigator s Global Assessment. The IGA mod 2011 rating scale: The IGA mod 2011 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 and 4 = severe. Based on this scale, a patient was considered as an IGA 0 or 1 responder if they achieved a score of 0 or 1 and improved by at least 2 points on the IGA scale at a given time point compared to their score at randomization (baseline).	Week 1, week 2, week 4, week, 8, week 12, week 16
Percentages of Subjects With ppIGA 0 or 1 Response (Observed Cases) - Treatment Period II	ppIGA: Palmoplantar Ivestigator s Global Assessment. The IGA mod 2011 rating scale: The IGA mod 2011 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 and 4 = severe. Based on this scale, a patient was considered as an IGA 0 or 1 responder if they achieved a score of 0 or 1 and improved by at least 2 points on the IGA scale at a given time point compared to their score at randomization (baseline).	Week 16, Week 20, Week 28, Week 32, Week 64, Week 132
Percentages of Subjects With ppIGA 0 or 1 Response (Observed Cases) - Entire	ppIGA: Palmoplantar Ivestigator s Global Assessment. The IGA mod 2011 rating scale: The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant s disease at the time of the assessment, and did not compare	Week 16, Week 24, Week

Treatment Period	with any of the participant s previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe. Based on this scale, a patient was considered as an IGA 0 or 1 responder if they achieved a score of 0 or 1 and improved by at least 2 points on the IGA scale at a given time point compared to their score at randomization (baseline).	28, Week 80
Absolute Change From Baseline for Palmoplantar Psoriasis Area and Severity Index (ppPASI) Score - Treatment Period I	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).	Week 1, Week 2, Week 4, Week 8, Week 12, Week 16
Absolute Change From Baseline for Palmoplantar Psoriasis Area and Severity Index (ppPASI) Score (Observed Cases) - Entire Treatment Set	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).	Week 16, Week 32, Week 80, Week 132
Number of Participants Developing Anti-secukinumab Antibodies	To investigate the development of immunogenicity against secukinumab	Over time up to week 132

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

2013-01-23

First Submitted that Met QC Criteria

2013-03-05

First Posted (Estimated)
2013-03-07

Results Reporting Dates

Results First Submitted
2017-10-31

Results First Submitted that Met QC Criteria
2018-01-22

Results First Posted
2018-02-22

Study Record Updates

Last Update Submitted that met QC Criteria
2018-01-22

Last Update Posted
2018-02-22

Last Verified
2018-01

More Information

Terms related to this study

Keywords Provided by Novartis (Novartis Pharmaceuticals)

Skin condition, itching, psoriasis vulgaris, relapsing remitting psoriasis, immune med systemic disease, skin lesions, scaly patches, papules, plaques

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

No study documents available

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COMPLETED

Pharmacokinetics of 122-0551 and Its Effects on Adrenal Suppression

ClinicalTrials.gov ID NCT01698333

Sponsor Therapeutics, Inc.

Information provided by Therapeutics, Inc. (Responsible Party)

Last Update Posted 2018 10 24

Study Details Tab

Study Overview

Brief Summary

Adrenal suppression effects of corticosteroids are among the most important safety concerns for this group of products. This study is designed to determine the adrenal effects of the investigational formulation of 122 0551 and characterize the steady state pharmacokinetics of the formulation.

Feedback

Official Title

An Open Label Evaluation of the Adrenal Suppression Potential and Pharmacokinetic Properties of Twice Daily 122 0551 in Subjects With Plaque Psoriasis Receiving Two Weeks of Treatment

Conditions

Plaque Psoriasis

Intervention / Treatment

- Drug: 122 0551

Other Study ID Numbers

- 122 0551 202

Study Start

2012 04

Primary Completion (Actual)

2013 03

Study Completion (Actual)

2013 07

Enrollment (Actual)

25

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)

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
Anaheim Clinical Trials

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

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 psoriasis therapy within 30 days prior to initiation of treatment
- Subject has used systemic corticosteroids or topical, inhaled, intranasal corticosteroids within 30 days and 14 days, respectively, prior to study screening
- Subject has had prolonged exposure to natural or artificial sources of ultraviolet radiation within 30 days prior to initiation of treatment
- Subject has used topical psoriatic therapy including tar, anthralin, retinoids, vitamin D analogs (e.g., Dovonex®) within 14 days prior to initiation of treatment
- Subject has used emollients/moisturizers on areas to be treated within one day prior to initiation of treatment
- Subject is currently using lithium or Plaquenil (hydroxychloroquine)
- Subject is currently using a beta blocking medication (e.g., propranolol) or angiotensin converting enzyme (ACE) inhibitors (e.g., lisinopril) at a dose that has not been stabilized
- Subject is pregnant, nursing or planning a pregnancy during the study period
- Subject is currently enrolled in an investigational drug, biologic or device study
- Subject has received an investigational drug, biologic or an investigational device within 30 days prior to study start
- Subject has been previously enrolled in this study and treated with the test article
- Subject has an irregular sleep schedule or works night shifts

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: 122-0551	Drug: 122-0551 • Applied twice daily for 2 weeks

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Hypothalamic-Pituitary-Adrenal (HPA) Axis Response	HPA axis response to stimulation by cosyntropin, dichotomized to "normal" and "abnormal". Laboratory evidence of abnormal HPA axis response is defined as a 30-minute post-stimulation serum cortisol level that is ≤ 18 µg/dL at the end of study.	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
2012-09-28

First Posted (Estimated)
2012-10-03

Results Reporting Dates

Results First Submitted
2018-08-30

Results First Submitted that Met QC Criteria
2018-08-30

Results First Posted
2018-09-26

Study Record Updates

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

Last Update Posted
2018-10-24

Last Verified
2018-09

More Information

Terms related to this study

Keywords Provided by Therapeutics, Inc.

122 0551
steroid
HPA

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

Use of Localized NB-UVB (Levia®) in the Treatment of Plaque-psoriasis

ClinicalTrials.gov ID **NCT02107482**

Sponsor Tufts Medical Center

Information provided by Tufts Medical Center (Responsible Party)

Last Update Posted 2017 03 31

Study Details Tab

Study Overview

Brief Summary

The purpose of the study is to test the effect of a localized narrow band ultraviolet (NB UVB) phototherapy compared to visible light that does not produce UVB on the clearance of psoriasis plaques and resolution of itching. Localized NB UVB (Levia®) phototherapy device is cleared by the U.S Food and Drug Administration (FDA).

Feedback

Detailed Description

This will be an ascending dose study with treatments three times per week, initial treatment dose and increasing regimen is adjusted according to the subject skin type. A suggested treatment regimen schedule provided from Lerner Medical Devices, Inc:

For subjects with skin type I: starting dose of 195 mj/cm2, for subjects with skin type II: starting dose of 330 mj/cm2, for subjects with skin type III: starting dose of 390 mj/cm2, for subjects with skin type IV: starting dose of 495 mj/cm2, for subjects with skin type V: starting dose of 525 mj/cm2, for subjects with skin type VI: starting dose of 600 mj/cm2.

The dose will be increased by 15% with each treatment, as long as there are no side effects with treatment such as burning or redness.

Official Title

Bilateral Comparator, Sham Light Source Controlled, Assessor Blinded Clinical Trial of Localized Narrow Band Ultraviolet B (NB UVB) (Levia®) Treatment for Plaque type Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Device: Levia Narrow Band UVB
- Device: Levia sham/visible light source

Other Study ID Numbers

- Levia

Study Start

2011 12

Primary Completion (Actual)

2014 12

Study Completion (Actual)

2014 12

Enrollment (Actual)

21

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)

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

Massachusetts Locations

Boston, Massachusetts, United States, 02111

Dermatology Research, Tufts Medical 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:

- Adults 18 years or older with bilateral psoriasis plaques, in general good health as determined by the Principal Investigator by medical history and physical exam.
- Able to understand consent procedure
- Able to comply with protocol activities
- Must have baseline symmetric target lesions with baseline Target Lesion Score (TLS) of 6 or higher (scale of 0 12), i.e., moderate in intensity for each target.

Target Lesion Scoring: Thickness, scaling and erythema of the plaques are rated each on a scale of 0 4. The three scores are summed. The minimum score is 0; the maximum is 12. Scores of 6 or greater are considered moderate to severe.

Exclusion Criteria:

- Patients less than 18 years old
- Patients not able to understand consent procedure
- Patients unable to comply with protocol activities
- Non English speakers: the study assessments/questionnaires/evaluations are not scientifically validated in languages other than English
- Baseline target lesions scores of less than 6
- Patients with a photosensitive disorder or on a medication which has been demonstrated in these patients to cause photosensitivity
- Patients receiving concomitant phototherapy to test sites
- Patient receiving topical medication to test sites within 2 weeks of study initiation
- Patient receiving Methotrexate, Acitretin, Cyclosporine, or other oral medications for psoriasis within 4 weeks of study initiation
- Patients receiving Etanercept (Enbrel®) within the past 2 months of study initiation
- Patients receiving Infliximab (Remicade®), Ustekinumab (Stelara®), Golimumab (Simponi®) Adalimumab (Humira®) or Alefacept (Amevive®) within the past 3 months prior to study initiation
- Receipt of an investigation agent within the past 4 weeks (or within 5 half lives) prior to study ignition
- Systemic corticosteroid therapy within the past month
- Concurrent use of prohibited medications

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
Active Comparator: Levia Narrow Band UVB Levia Narrow Band UVB dosing for subjects with skin type I: starting dose of 195 mj/cm2, for subjects with skin type II: starting dose of 330 mj/cm2, for subjects with skin type III: starting dose of 390 mj/cm2, for subjects with skin type IV: starting dose of 495 mj/cm2, for subjects with skin type V: starting dose of 525 mj/cm2, for subjects with skin type VI: starting dose of 600 mj/cm2. The dose will be increased by 15% with each treatment, as long as there are no side effects with treatment such as burning or redness.	Device: Levia Narrow Band UVB • The device s spectral output is is Narrow Band UVB (NB-UVB) (NB-Levia): 308-312 nm
Sham Comparator: Levia sham/visible-light source	Device: Levia sham/visible-light source • the light spectrum is in the range of 400-700nm, the light is produced using the same Levia® device. Levia® enable the

the light is produced using the same Levia® device. Levia® enable the user to switch off the UVB light and only produce visible light spectrum.	user to switch off the UVB light and only produce visible light spectrum.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Percentage of Lesions With a Clear or Almost Clear Rating (Target Lesion Score of 3 or Less) on Target Lesion Scoring at Week 12		12 weeks

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Percentage of Change in Target Lesion Score		12 weeks
Changes in Target Lesion Pruritus Visual Analog Scale		12 weeks

(VAS) at Week 12		

Collaborators and Investigators

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

Sponsor

Tufts Medical Center

Collaborators

No information provided

Investigators

- Principal Investigator: Alice b Gottlieb, MD, PhD, Tufts Medical Center

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
2014-04-04

First Submitted that Met QC Criteria
2014-04-04

First Posted (Estimated)
2014-04-08

Results Reporting Dates

Results First Submitted
2016-09-28

Results First Submitted that Met QC Criteria
2016-12-27

Results First Posted
2017-02-20

Study Record Updates

Last Update Submitted that met QC Criteria
2017-03-02

Last Update Posted
2017-03-31

Last Verified
2017-03

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

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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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

A 12 Day Study To Evaluate A Topical Drug To Treat Plaque Psoriasis

ClinicalTrials.gov ID NCT02193815

Sponsor Pfizer

Information provided by Pfizer (Respons b e Party)

Last Update Posted 2016 06 09

Study Details Tab

Study Overview

Brief Summary

Th s s a veh c e and comparator contro ed Proof of Mechan sm (PoM) tr a to eva uate the effect on psor as s d sease act v ty and safety of top ca y app ed PF 06263276 n subjects w th psor as s vu gar s

Official Title

A Phase 1, S ng e Center, Random zed, Doub e b nd, Veh c e And Act ve Comparator contro ed Tr a To Eva uate The Ant psor at c Act v ty And Safety Of A Top ca y App ed Pf 06263276 Formu at on n A Psor as s P aque Test

Conditions

Psor as s Vu gar s

Intervention / Treatment

- Drug PF06263276
- Other Veh c e
- Drug 2%Tofac t n b O ntment
- Other Veh c e
- Drug Da vonex
- Drug Da vonex O ntment

Other Study ID Numbers

- B5391003
- 2014 000068 16 (EudraCT Number)

Feedback

Study Start

2014 09

Primary Completion (Actual)

2015 02

Study Completion (Actual)

2015 02

Enrollment (Actual)

15

Study Type

ntervent ona

Phase

Phase 1

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)

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

Hamburg, Germany, 20095
Bioskin GmbH

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

- Hea thy ma e and/or fema e subjects age 18 years and o der, nc us ve Hea thy s defined as no c n ca y re evant abnorma t es dent fied by a deta ed med ca h story, fu phys ca exam nat on, nc ud ng b ood pressure and pu se rate measurement, 12 ead ECG or c n ca aboratory tests
- Subjects w th psor as s vu gar s n a chron c stab e phase and w th a p aque area of m d to moderate sever ty suffic ent for s x treatment fie ds ocated n up to three p aque areas
- The target es on(s) shou d be on the trunk or extrem t es (exc ud ng pa ms/so es) Psor at c es ons on the knees or e bows are not to be used as a target es on

Exc us on Cr ter a

- Subjects w th psor as s guttata, psor as s punctata, psor as s erythrodermat ca, psor as s arthropath ca and pustu ar psor as s
- Treatment w th any system c med cat ons wh ch n the op n on of the nvest gator m ght counter or nfluence the tr a a m (nc ud ng ant psor as s med cat ons, eg, cort costero ds, cytostat cs or ret no ds) or med cat ons wh ch are known to provoke or aggravate psor as s (eg, beta b ocker, ant ma ar a drugs, th um) or phototherapy/psora en+UVA (PUVA) w th n 4 weeks preced ng the treatment phase of the tr a and dur ng the tr a
- Treatment w th any oca y act ng med cat ons (nc ud ng ant psor as s med cat ons ke v tam n D ana ogues, d thrano) w th n 4 weeks of the treatment phase

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 : Para e Ass gnment
Masking : Doub e (Part c pant, nvest gator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Exper menta One Arm Study treatments 1-6 Study drug, veh c e, Tofac t n b, veh c e, Da vonex so ut on and o ntment	Drug PF06263276 • 4% PF 06263276 so ut on Da y dosage approx mate y 8 mg PF 06263276 QD Other Veh c e • Act ve ngred ent-free veh c e to 4% so ut on Drug 2%Tofac t n b O ntment • Da y Dosage approx mate y 4 mg tofac t n b Other Veh c e • Act ve ngred ent-free veh c e to 2% O ntment Drug Da vonex • Da vonex so ut on (50 ug/m Ca c potr o) Da y Dosage of ca c potr o approx mate y 0 01 mg Drug Da vonex O ntment • Da vonex o ntment (50 ug/g Ca c potr o) Da y Dosage of ca c potr o approx mate y 0 01 mg

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Base ne n Psor at c Sk n Th ckness/Echo-Poor Band (EPB) for PF-06263276 4% So ut on n Compar son to Correspond ng Veh c e at Day 12	Psor at c sk n th ckness was measured us ng a 20 megahertz (MHz) h gh frequency sonograph Ser a A-scans were composed and presented on a mon tor as a sect on of the sk n	Day 1 (Base ne), Day 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Base ne n Psor at c Sk n Th ckness/EPB for PF-06263276 4% So ut on n Compar son to Da vonex So ut on at Day 12		Day 1 (Base ne), Day 12
Change From Base ne n Psor at c Sk n Th ckness/EPB for Tofac t n b 2% O ntment n		Day 1 (Base ne), Day 12

Compar son to Correspond ng Veh c e at Day 12		
Change From Base ne n Psor at c Sk n Th ckness/EPB at Day 8		Day 1 (Base ne), Day 8
Area Under the Curve (AUC) of Psor at c Sk n Th ckness/EPB	The AUC of psor at c sk n th ckness/EPB from Day 1 to Day 12 was determ ned us ng the near trapezo da ru e The mean raw va ues are reported	Day 1 (base ne) up to Day 12
G oba C n ca Assessment at Day 1, 8 and 12	G oba C n ca Assessment of the test fie ds was performed by v sua exam nat on us ng a 5-po nt score (-1=worsened; 0=unchanged [no effect]; 1=s ght mprovement; 2=c ear mprovement but not comp ete y hea ed; 3=comp ete y hea ed) C n ca y apparent d fferences n erythema and nfi trat on w contr bute to th s g oba assessment At base ne (Day 1), the score was documented as 0 (unchanged)	Day 1, Day 8, Day 12

Other Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Part c pants W th Treatment-Emergent Adverse Events (AEs) or Ser ous Adverse Events (SAEs) Spec fied Sk n AEs	An AE was any untoward med ca occurrence n a part c pant who rece ved study drug 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 Treatment-emergent are events between first dose of study drug and up to 28 days after ast dose that were absent before treatment or that worsened re at ve to pre-treatment state AEs nc uded both SAEs and non-SAEs The number of part c pants w th spec fied sk n AEs was reported	Base ne up to 28 days after ast study drug adm n strat on (Day 21)
Number of Part c pants W th Laboratory Abnorma t es Meet ng the Cr ter a for Potent a C n ca Concern	The fo ow ng aboratory parameters were ana yzed hemato ogy (hemog ob n, hematocr t, red b ood ce [RBC] count, RBC morpho ogy, p ate et count, wh te b ood ce [WBC] count, tota neutroph s, eos noph s, monocytes, basoph s, ymphocytes); b ood chem stry (b ood urea n trogen [BUN], creat n ne, g ucose, ca c um, sod um, potass um, ch or de, tota b carbonate, aspartate am notransferase [AST], a an ne am notransferase [ALT], tota b rub n, a ka ne phosphatase, ur c ac d, a bum n, and tota prote n; ur na ys s (pH, g ucose, prote n, b ood, ketones, n tr tes, eukocyte esterase, urob nogen, ur ne b rub n, m croscopy [f ur ne d pst ck was pos t ve for b ood, prote n, n tr tes or eukocyte esterase]); others (e g , ur ne human chor on c gonadotrop n [hCG] for fema es of ch dbear ng potent a)	Base ne up to Day 12
Number of Part c pants W th Potent a y C n ca y S gn ficant V ta S gns F nd ngs	V ta s gns assessment nc uded pu se rate and b ood pressure Cr ter a for v ta s gn va ues meet ng potent a c n ca concern nc uded sup ne/s tt ng pu se rate <40 or >120 beats per m nute (bpm), stand ng pu se rate <40 or >140 bpm; systo c b ood pressure (SBP) >=30 m meters of mercury (mmHg) change from base ne n same posture or SBP <90 mmHg, d asto c b ood pressure (DBP) >=20 mmHg change from base ne n same posture or DBP <50 mmHg	Base ne up to Day 12

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
2014-07-16

First Submitted that Met QC Criteria
2014-07-16

First Posted (Estimated)
2014-07-18

Results Reporting Dates

Results First Submitted
2016-03-04

Results First Submitted that Met QC Criteria
2016-05-02

Results First Posted (Estimated)
2016-06-09

Study Record Updates

Last Update Submitted that met QC Criteria
2016-05-02

Last Update Posted (Estimated)
2016-06-09

Last Verified
2016-05

More Information

Terms related to this study

Keywords Provided by Pfizer

psor as s
p aque
vu gar s
phase 1
random zed
doub e b nd
top ca
safety

Additional Relevant MeSH Terms

Sk n D seases, Papu osquamous
Sk n D seases
Psor as s
Janus K nase nh b tors
Prote n K nase nh b tors
Enzyme nh b tors
Mo ecu ar Mechan sms of Pharmaco og ca Act on
Dermato og c Agents
Ca c um Regu at ng Hormones and Agents
Phys o og ca Effects of Drugs
Ca c um Channe Agon sts
Membrane Transport Modu ators
Vasoconstr ctor Agents
V tam ns
M cronutr ents
Bone Dens ty Conservat on Agents
Ca c tr o
Ca c potr ene
Tofac t n b

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=B5391003&StudyName=A%2012%20Day%20Study%20To%20Eva uate%20A%20Top ca %20Drug%20To%20Treat%20P aque%20Psor as s)

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Go to the classic website

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

Quality of Life in Adalimumab Treated Psoriasis Patients Failing Other Biologic Disease Modifying Anti-rheumatic Drugs (QUALITY)

ClinicalTrials.gov ID **NCT01084668**

Sponsor Abbott

Information provided by Abbott (Responsible Party)

Last Update Posted 2012 06 29

Study Details Tab

Study Overview

Brief Summary

The aim of this post marketing observational study (PMOS) was to obtain further data on long term safety, efficacy, and quality of life outcomes for adalimumab in routine clinical use in participants with moderate to severe chronic plaque psoriasis after unsustainable clinical response to other

Feedback

biologic disease modifying anti rheumatic drugs (BDMARDs). There are few data so far showing the effects of switching from other BDMARDs to adalimumab in patients with moderate to severe chronic plaque psoriasis. This study was designed to evaluate the long term effectiveness of adalimumab in participants with moderate to severe chronic plaque psoriasis using the Psoriasis Area and Severity Index (PASI) in participants previously treated with efalizumab, infliximab, or etanercept and who either never achieved satisfactory response, achieved satisfactory response initially but lost it over time, or discontinued treatment due to intolerance/side effect(s) or other reasons, for example after regular stop of etanercept.

Detailed Description

This was a non interventional PMOS conducted in a prospective, single country, multicenter format to assess the quality of life of psoriasis patients taking adalimumab as prescribed by their physician in accordance with the terms of the local marketing authorization with regard to dose, population, and indication. The prescription of adalimumab was clearly separated from the decision to include the participant in this study. No procedures other than standard of care were to have been performed. Visits were non interventional and timing of participant appointments was left to each physician. After therapy initiation, visits occurred over 12 months usually close to Weeks 4, 12, 24, 36, and 52 for a total of 6 visits (Visits 1 through 6 including Screening). Because participant visits were left to the physician, participant failure to meet the suggested visit weeks did not constitute a breach of the protocol.

Official Title

A Post marketing Observational Study of the Quality of Life in Adalimumab Treated Psoriasis Patients Failing Other Biologic DMARDs Over a Period of 1 Year (QUALITY)

Conditions

Psoriasis Chronic

Intervention / Treatment

Other Study ID Numbers

- P10 708

Study Start

2008 11

Primary Completion (Actual)

2011 04

Study Completion (Actual)

2011 04

Enrollment (Actual)

46

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.

Austria

Feldkirch, Austria, 6807
Site Reference ID/Investigator# 27435

Graz, Austria, 8010
Site Reference ID/Investigator# 27436

Graz, Austria, 8036
Site Reference ID/Investigator# 38445

Linz, Austria, 4020
Site Reference ID/Investigator# 27443

Vienna, Austria, 1030
Site Reference ID/Investigator# 27442



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 for whom adalimumab therapy is indicated and has been prescribed according to the product label
- Patients aged 18 years and older
- Unsatisfactory response to prior BDMARDS (efalizumab, infliximab, etanercept) in patients with moderate to severe chronic plaque psoriasis or achievement of satisfactory response initially, but loss over time or discontinuation of treatment due to intolerance/side effects(s) or other reasons e.g. restart after regular stop of etanercept
- Patients must fulfill Austrian Treatment Recommendations for use of BDMARD in psoriasis (chest X ray and purified protein derivative [PPD] skin test negative for tuberculosis)
- Patient is willing to consent to data being collected and provided to Abbott
- Patient must be able and willing to self administer Pen injections or have a qualified person available to administer Pen injections

Exclusion Criteria:

- Patients who meet contraindications as outlined in the latest version of the Humira Pen Summary of Product Characteristics (SPC)
- Patients who do not meet the criteria for the use of BDMARDs of the Austrian Treatment Recommendations
- Patients participating in another study or clinical trial

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
Adalimumab Participants with moderate to severe chronic plaque psoriasis treated with adalimumab after biologic disease modifying anti-rheumatic drug (BDMARD) failure

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Psoriasis Area and Severity Index (PASI) Score	Psoriasis Area and Severity Index (PASI) score is based on assessment of erythema (reddening), induration (plaque thickness), desquamation (scaling), and area affected as observed on the day of examination. The score ranges from 0 (best outcome) to 72 (worst outcome).	Inclusion visit (Week 0), Week 4, Week 36, Week 52

Reduction in Psoriasis Area and Severity Index Score of at Least 75% (PASI75)	PASI75 is the number of participants who achieved at least a 75% reduction (improvement) from baseline in PASI score at Week 52 (final visit). PASI score is based on assessment of erythema (reddening), induration (plaque thickness), desquamation (scaling), and area affected as observed on the day of examination. The score ranges from 0 (best outcome) to 72 (worst outcome).	Inclusion visit (Week 0) to Week 52

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Dermatology Life Quality Index (DLQI) Score	Dermatology Life Quality Index (DLQI) Score is a participant-reported outcome consisting of a set of 10 questions regarding the degree to which the participant s skin has affected certain behaviors and quality of life over the last week. Responses to each are: very much, a lot, a little, or not at all. The DLQI score ranges from 0 (best) to 30 (worst).	Inclusion visit (Week 0), Week 4, Week 36, Week 52
Nail Psoriasis Severity Index (NAPSI) Score	The nails are graded for nail matrix psoriasis and nail bed psoriasis. The sum of these two scores is the total score for that nail. Per nail, the NAPSI score ranges from 0 (no nail psoriasis) to 4 (most severe nail psoriasis).	Inclusion visit (Week 0), Week 4, Week 36, and Week 52

Tolerability and Safety Assessed by Collection and Classification of Adverse Reactions	Tolerability and safety were assessed by collecting adverse events during the course of the study up to 70 days following the last dose of physician-prescribed adalimumab. The number of participants experiencing a serious or non-serious adverse event is summarized. See the Reported Adverse Event section for details.	From the time of participant consent until 70 days after last dose of study drug

Collaborators and Investigators

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

Sponsor

Abbott

Collaborators

- Assign Data Management and Biostatistics GmbH

Investigators

- Study Director: Astrid Dworan Timler, MD, Abbott Austria

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
2010-02-28

First Submitted that Met QC Criteria
2010-03-09

First Posted (Estimated)
2010-03-10

Results Reporting Dates

Results First Submitted
2012-04-26

Results First Submitted that Met QC Criteria
2012-04-26

Results First Posted (Estimated)
2012-05-30

Study Record Updates

Last Update Submitted that met QC Criteria
2012-06-25

Last Update Posted (Estimated)
2012-06-29

Last Verified
2012-06

More Information

Terms related to this study

Keywords Provided by Abbott

moderate to severe chronic plaque psoriasis
adalimumab
Psoriasis Area and Severity Index (PASI)
Disease Life Quality Index (DLQI)
Nail Psoriasis Severity Index (NAPSI)
biologic disease modifying anti rheumatic drug (BDMARD)
antibodies
monoclonals

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

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

ClinicalTrials.gov ID NCT01309737

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

A Phase 3, Multi-Site, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Of The Efficacy And Safety Of 2 Oral 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

- A3921079

Study Start

2011-03

Primary Completion (Actual)

2013-04

Study Completion (Actual)

2013-04

Enrollment (Actual)

960

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, 35233
Un vers ty of A abama at B rm ngham

Arkansas Locations

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

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 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:

- 18 years or older with diagnosis for at least 12 months of moderate to severe plaque psoriasis covering at least 10% of body surface area
- A Psoriasis Area and Severity Index (PASI) score of 12 or greater
- Are considered to be candidates for systemic or light therapy
- Have 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: Active Treatment 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 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,	Week 16

	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.	Baseline, 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 Psoriasis Area and Severity Index 75 (PASI 75) Response at Week 4	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 body region and for the proportion of the body region to the whole body. The PASI score can	Week 4

	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% 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 Maintaining Psoriasis Area and Severity Index 75 (PASI 75)	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	Week 52

Response at Week 52	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 P oria i 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	Baseline up to Week 16

	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 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 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% 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 relative to Baseline. The median time to event was estimated based on the probability	Baseline up to Week 16

	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 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 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	Week 2, 4, 8, 12, 16, 20, 28, 40, 52

	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 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 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 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 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 and 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 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 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 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, 8,16, 20, 28, 40, 52
Percent Change From Baseline in	Assessment of BSA with psoriasis was estimated by means of the handprint method, where the full palmar	Baseline, Week 2, 4, 8,

Total Body Surface Area (BSA) With Psoriasis at Week 2, 4, 8, 12, 16, 20, 28, 40 and 52	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.	12, 16, 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 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 50 response was defined as at least a 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 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 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	Week 2, 4, 8,12,16, 20, 28, 40, 52

	90% reduction in PASI relative to Baseline. Percentage of participants with PASI 90 response is reported.	
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 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).	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. n signifies participants evaluable at specified time point for each arm.	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. n signifies	Baseline,Week 8, 16, 20, 28, 40, 52

	participants evaluable at specified time point for each arm.	
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 of psoriasis affected nails (presence of psoriatic manifestations on the nail matrix / nail bed) were assessed and reported. N (number of participants analyzed) signifies participants (with baseline nail psoriasis) who were evaluable for this measure.	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. N (number of participants analyzed) signifies participants with baseline nail psoriasis and who were unique in longitudinal model.	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	Week 8, 16, 20, 28, 40, 52

	was defined as at least a 75% reduction in NAPSI relative to Baseline. Percentage of participants with NAPSI 75 response is reported. N(number of participants analyzed) signifies participants (with baseline nail psoriasis) who were evaluable for this measure.	
Percentage of Participants With Nail Psoriasis Severity Index 100 (NAPSI 100) 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 100 response was defined as at least a 100% reduction in NAPSI relative to Baseline. Percentage of participants with NAPSI 100 response is reported. N(number of participants analyzed) signifies participants (with baseline nail psoriasis) who were evaluable for this measure.	Week 8,16, 20, 28, 40, 52
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 general dermatology questionnaire that consists of 10 items 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 Week 2, 4, 8, 12, 16, 20, 28, 40 and 52	The DLQI is a general dermatology questionnaire that consists of 10 items 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. Here N (number of participants analyzed) signifies the unique participants in the longitudinal model.	Baseline, Week 2, 4, 8, 12, 16, 20, 28, 40, 52
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 options ranging from 0 (no presence of anxiety or depression) to 3 (severe feeling of anxiety or depression). Total HADS score ranges from 0 to 21 for each subscale; higher score indicates greater severity of anxiety and depression symptoms.	Baseline, Week 8, 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	Baseline, Week 8, 16, 28, 52

	(6 item); 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]).	
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 8,16, 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 and 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. 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. Here N (number of participants analyzed) signifies participants evaluable for this measure.	Baseline, Week 16
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 (currently employed [Emp]) answered (Yes/No [Y/N]): "Were you absent or on sick leave from work due to psoriasis today?", and participants (unemployed [UEmp]) 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	The Psoriasis Health Care Resource Utilization (Ps HCRU) questionnaire is a short questionnaire	Week 16

Resource Utilization Questionnaire (Ps HCRU) Healthcare Resource Use Events and Employment Status	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.	
Psoriasis Healthcare Resource Utilization Questionnaire (Ps HCRU) Work Hours and 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. 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. Here N (number of participants analyzed) signifies participants evaluable for this measure.	Baseline, Week 16
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	Baseline, Week 16

	Week 16 as per study teams decision because Week 0 16 period was considered sufficient to provide clear reflection of Ps HCRU endpoint. Here N (number of participants analyzed) signifies participants evaluable for this measure.	
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. Here N (number of participants analyzed) signifies participants evaluable for this measure.	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

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Study Registration Dates

First Submitted
2011 03 04

First Submitted that Met QC Criteria
2011 03 04

First Posted (Estimated)
2011 03 07

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
Jak-inhibitor
oral treatment
chronic
severe
moderate
Pruritus
Itch
DLQI
treatment
safety
efficacy
CP-690,550
Plaque Psoriasis
Psoriasis Vulgaris

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_A3921079&StudyName_A%20One-Year%20Study%20To%20Evaluate%20The%20Efficacy%20And%20Safety%20Of%20CP-690%2C550%20For%20Patients%20With%20Moderate%20To%20Severe%20Chronic%20Plaque%20Psoriasis)

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

A Study of the Efficacy and Safety of DFD-06 Cream in the Treatment of Moderate to Severe Plaque Psoriasis

ClinicalTrials.gov ID **NCT02445807**

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

Chronic Stable Plaque Psoriasis

Intervention / Treatment

- Drug: DFD06 Cream
- Drug: Vehicle Cream

Other Study ID Numbers

- DFD06 CD 005

Study Start

2015 12

Primary Completion (Actual)

2016 07

Study Completion (Actual)

2016 07

Enrollment (Actual)

265

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: 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

Alabama Locations

Birmingham, Alabama, United States, 35205
Site 101

Mobile, Alabama, United States, 36608
Site 103

Arizona Locations

Mesa, Arizona, United States, 85202

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 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
Efficacy (Percentage of Subjects With Treatment Success)	The primary efficacy endpoint is 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. The 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
The Percent Change in Body Surface Area of Psoriasis	The percent change from baseline in Body Surface Area at Day 15. The analysis was done with multiple imputations. Results are combined analyses from 5 imputed data sets.	From Baseline to Day 15
The Percentage of Subjects With Treatment Success at the Day 8 Visit.	The percentage of subjects with treatment success (defined as IGA = 0 or 1 and at least a 2 grade reduction from Baseline) at Day 8. The analysis was done with multiple imputations. Results are combined analyses from 5 imputed data sets.	At Day 8 Visit

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

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Study Registration Dates

First Submitted
2015-05-13

First Submitted that Met QC Criteria
2015-05-14

First Posted (Estimated)
2015-05-15

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

A Study to Evaluate the Safety and Effectiveness of Doxercalciferol Capsules in Participants With Moderate to Severe Psoriasis

ClinicalTrials.gov ID NCT00601107

Sponsor Genzyme, a Sanofi Company

Information provided by Sanofi (Genzyme, a Sanofi Company) (Responsible Party)

Last Update Posted 2014 05 05

Study Details Tab

Study Overview

Brief Summary

Feedback

The purpose of this study was to evaluate the safety and effectiveness of an investigational drug called doxercalciferol in participants with moderate to severe chronic plaque psoriasis, in comparison with a placebo ("sugar pill"). All study related care was provided including doctor visits, physical exams, laboratory tests and study medication. Total length of participation was 28 weeks.

Detailed Description

This was a multicenter, randomized, double blind, placebo controlled, dose ranging, parallel group study to evaluate the efficacy and safety of doxercalciferol given orally, once daily for 24 weeks to participants with moderate to severe chronic plaque psoriasis. Participants were randomized and stratified by site and Psoriasis Area Severity Index (PASI) score to one of three active treatment groups or to the placebo group.

Official Title

A Multicenter, Double Blind, Placebo Controlled, Dose Ranging Study to Assess the Efficacy and Safety of Doxercalciferol Capsules in the Treatment of Subjects With Moderate to Severe Chronic Plaque Psoriasis

Conditions

Moderate to Severe Chronic Plaque Psoriasis

Intervention / Treatment

- Drug: Doxercalciferol
- Drug: Placebo

Other Study ID Numbers

- HECTPS02507

Study Start

2008 04

Primary Completion (Actual)

2009 02

Study Completion (Actual)

2009 06

Enrollment (Actual)

111

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

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

Arizona Locations

Hot Springs, Arizona, United States

Arkansas Locations

Little Rock, Arkansas, United States

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:

- Participant had moderate to severe chronic plaque psoriasis defined by a body surface area (BSA) involvement greater than or equal to (>=) 10 percent (%) and plaques with at least a slight elevation above the surrounding normal skin at the Day 1 visit
- Participant had a static Physicians Global Assessment (PGA) of moderate or severe at the Day 1 visit
- Participant had a minimum PASI score of 10 at the Day 1 visit
- Participant was a candidate to receive systemic psoriasis therapy in the opinion of the Investigator
- Participant of childbearing potential, was willing to use an effective contraceptive method throughout the study, which included barrier methods, hormones, or intrauterine devices

Exclusion Criteria:

- Used vitamin D analogues, multivitamin supplements containing greater than (>) 400 international unit (IU) vitamin D, topical retinoids, topical pimecrolimus, and topical tacrolimus within 14 days prior to the Day 1 visit
- Used drugs known to influence serum calcium (such as lithium, digoxin, thiazide diuretics, teriparatide, bisphosphonates, and calcitonin) and multivitamin supplements containing calcium and/or calcium containing antacids exceeding a total of 1 gram/day within 14 days prior to the Day 1 visit
- Used keratolytics or coal tar (except shampoo containing coal tar or salicylic acid) within 14 days prior to the Day 1 visit
- Used low potency topical corticosteroids (Classes VI and VII), except on the groin, scalp, palms, soles and face, within 14 days prior to the Day 1 visit
- Used medium potency topical corticosteroids (Classes III V) or high potency topical corticosteroids (Classes I and II) within 14 days prior to the Day 1 visit
- Used systemic retinoids, systemic corticosteroids, methotrexate, cyclosporine, azathioprine, thioguanine or other systemic immunosuppressant agents within 28 days prior to the Day 1 visit
- Used phototherapy, including Ultraviolet B within 14 days or Psoralen plus Ultraviolet A within 28 days prior to the Day 1 visit
- Used a biological agent (including, but not limited to, etanercept, adalimumab, efalizumab, infliximab, or alefacept) within 5 half lives of the drug prior to the Day 1 visit
- Used systemic antibiotics within 14 days prior to the Day 1 visit. Antibiotic treatment of infections during the Treatment Period was not excluded
- Used investigational drugs within 28 days prior to the Day 1 visit
- Current erythrodermic, guttate, generalized pustular, unstable psoriasis or other chronic active skin conditions that may interfere with the study
- Screening visit laboratory result exceeded the following limits: alanine transaminase (ALT) or aspartate transaminase (AST) >1.5 times the upper limit of normal (ULN);

bilirubin >ULN; serum creatinine, calcium, or phosphorus >ULN; spot urine calcium/creatinine ratio >0.4
- History of nephrolithiasis
- Chronic kidney disease as evidenced by a calculated glomerular filtration rate (GFR) less than (<) 60 milliliter/minute/1.73 square meter (mL/min/1.73 m^2) at the screening visit
- Symptomatic coronary or cerebral vascular disease, human immunodeficiency virus, active viral hepatitis, or any other clinically significant, unstable medical condition that would interfere with the completion of the study
- Clinically significant electrocardiogram (EKG) abnormality at screening
- Any evidence of active malignancy except for basal cell carcinoma of the skin. A history of malignancy was not an exclusion
- Active ethanol or drug abuse, excluding tobacco use
- Active severe psychiatric illness that could interfere with the conduct of the study
- Pregnant or breast feeding women
- Known allergy or hypersensitivity to vitamin D or other ingredients in the study drug formulation

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: Doxercalciferol 2.5 mcg/day Doxercalciferol 2.5 microgram (mcg) capsule orally once daily up to Week 24.	Drug: Doxercalciferol • Other Names: ◦ Hectorol®
Experimental: Doxercalciferol 5 mcg/day Doxercalciferol 5 mcg capsules orally once daily up to Week 24.	Drug: Doxercalciferol • Other Names: ◦ Hectorol®
Experimental: Doxercalciferol 7.5 mcg/day Doxercalciferol 7.5 mcg capsules orally once daily up to Week 24.	Drug: Doxercalciferol • Other Names: ◦ Hectorol®
Placebo Comparator: Placebo Placebo matching to doxercalciferol capsules orally once daily up to Week 24.	Drug: Placebo

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With at Least 50 Percent (%) Reduction in Psoriasis Area Severity Index (PASI) Score at Week 12 or Early Termination	PASI score: range: 0 (no disease) to 72 (maximal disease). Body was divided into head (h), trunk (t), upper (u) and lower (l) extremities. For each section, percent area of skin involved (A) was estimated: 1 (<10%) to 6 (90% - 100%), and severity was estimated by clinical signs: (erythema [E], induration [I], and desquamation [D]) on a scale: 0=no symptoms, 4=very marked. PASI score= 0.1 (E[h] + I[h] + D[h]) A[h] + 0.2 (E[u] + I[u] + D[u]) A[u] + 0.3 (E[t] + I[t] + D[t]) A[t] + 0.4 (E[l] + I[l] + D[l]) A[l].	Week 12 or Early Termination

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With at Least 50 Percent (%) Reduction in Psoriasis Area Severity Index (PASI) Score at Week 24 or Early Termination	PASI score: range: 0 (no disease) to 72 (maximal disease). Body was divided into head (h), trunk (t), upper (u) and lower (l) extremities. For each section, percent area of skin involved (A) was estimated: 1 (<10%) to 6 (90% - 100%), and severity was estimated by clinical signs: (erythema [E], induration [I], and desquamation [D]) on a scale: 0=no symptoms, 4=very marked. PASI score= 0.1 (E[h] + I[h] + D[h]) A[h] + 0.2 (E[u] + I[u] + D[u]) A[u] + 0.3 (E[t] + I[t] + D[t]) A[t] + 0.4 (E[l] + I[l] + D[l]) A[l].	Week 24 or Early Termination
Percentage of Participants With Static Physician's	Static PGA of psoriasis is scored on a 5-point scale (0 = clear to 4 = severe), reflecting a global consideration of the erythema, induration and scaling across all psoriatic	Week 12 or Early Termination, Week 24 or

Global Assessment (PGA) Score of Clear or Almost Clear at Week 12, 24 or Early Termination	lesions. Clear (erythema: no, scale: no, induration: no thickness); Almost Clear (erythema: light pink, scale: fine scale, induration: barely palpable); Mild (erythema: light red, scale: coarse scale on most lesions, induration: slight but visible elevation, indistinct edges); Moderate (erythema: red, scale: coarse adherent scale predominates, induration: moderate elevation with edges); and Severe (erythema: dark red to purple, scale: thickened adherent scale, induration: marked thickness distinct and pronounced edges). Percentage of participants with static PGA score of clear or almost clear are reported.	Early Termination

Collaborators and Investigators

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

Sponsor

Genzyme, a Sanofi Company

Collaborators

No information provided

Investigators

- Study Director: Medical Monitor, Genzyme, a Sanofi Company

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
2008-01-15

First Submitted that Met QC Criteria
2008-01-24

First Posted (Estimated)
2008-01-25

Results Reporting Dates

Results First Submitted
2014-04-02

Results First Submitted that Met QC Criteria
2014-04-02

Results First Posted (Estimated)
2014-05-05

Study Record Updates

Last Update Submitted that met QC Criteria
2014-04-02

Last Update Posted (Estimated)
2014-05-05

Last Verified
2014-04

More Information

Terms related to this study

Keywords Provided by Sanofi (Genzyme, a Sanofi Company)

psoriasis
psoriasis vulgaris
plaque psoriasis
chronic plaque psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Vitamins
Micronutrients
Physiological Effects of Drugs
Bone Density Conservation Agents
1 alpha hydroxyergocalciferol

Study Documents

No study documents available

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COMPLETED

A Psoriasis Plaque Test Study With LEO 90100 Cutaneous Spray, Ointment, in Psoriasis Vulgaris

ClinicalTrials.gov ID **NCT01347255**

Sponsor LEO Pharma

Information provided by LEO Pharma (Responsible Party)

Last Update Posted 2016 08 15

Study Details Tab

Study Overview

Brief Summary

The purpose of the study is to evaluate the anti psoriatic effect of LEO 90100 cutaneous spray ointment, using the psoriasis plaque test modified from the method developed by KJ Dumas and JR Scholtz.

Feedback

Official Title

A Psoriasis Plaque Test Study With LEO 90100 Cutaneous Spray, Ointment, in Psoriasis Vulgaris

Conditions

Psoriasis Vulgaris

Intervention / Treatment

- Drug: LEO90100 cutaneous spray, ointment
- Drug: LEO 90100 cutaneous spray, ointment, vehicle with betamethasone dipropionate
- Drug: LEO 90100 cutaneous spray, ointment, vehicle
- Drug: Daivobet® ointment

Other Study ID Numbers

- LEO 90100 01
- 2011 000153 23

Study Start

2011 05

Primary Completion (Actual)

2011 06

Study Completion (Actual)

2011 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)

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, Cedex 3
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. Subjects having signed and dated an informed consent
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.

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, ichthyosis, 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: LEO 90100 cutaneous spray ointment LEO 90100 cutaneous spray, ointment, is a new product containing calcipotriol 50 mcg/g and betamethasone 0.5 mg/g (as dipropionate).	Drug: LEO90100 cutaneous spray, ointment • once daily application, 4 weeks
Active Comparator: LEO 90100 Cutaneous Spray, Ointment, Vehicle w. Betamethasone Vehicle cutaneous spray, ointment, with betamethasone 0.5 mg/g (as dipropionate)	Drug: LEO 90100 cutaneous spray, ointment, vehicle with betamethasone dipropionate • once daily application, 4 weeks
Placebo Comparator: LEO 90100 Cutaneous Spray, Ointment, Vehicle LEO 90100 vehicle served as a negative control for the two cutaneous spray ointments with active ingredients.	Drug: LEO 90100 cutaneous spray, ointment, vehicle • once daily application, 4 weeks

Active Comparator: Daivobet® Ointment Calcipotriol 50 mcg/g plus betamethasone 0.5 mg/g (as dipropionate)	Drug: Daivobet® ointment • once daily application, 4 weeks • Other Names: ◦ Taclonex® ointment

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Absolute Change in Total Clinical Score (TCS) of Clinical Signs (Sum of Erythema, Scaling and Infiltration) at End of Treatment Compared to Baseline	TCS range from 0 (all signs absent) to 9 (all signs severe).	Day 1 (Baseline)/Day 29

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change in Clinical Sign Scores	Absolute change in score of each clinical sign (erythema, scaling, infiltration) at end of treatment (Day 29) and at individual visits (Days 4, 8, 11, 15, 18, 22, and 25) compared to Baseline.	Baseline and Days 4, 8, 11, 15, 18, 22, 25, and 29

	The investigator assessed the severity of the clinical signs erythema, scaling, and infiltration for each test site by using a 7-point scale (range 0 (no evidence) to 3 (severe)). Negative changes in mean score represent improvement.	(End of Treatment)
Changes in Total Clinical Score (TCS) by Visit	Change in Total Clinical Score (TCS; range from 0 (all signs absent) to 9 (all signs severe)) at individual visits (Days 4, 8, 11, 15, 22, and 25) compared to baseline.	Baseline and Days 4, 8, 11, 15, 18, 22, 25
Change From Baseline in Echo-poor Band Thickness at End of Treatment	Change in echo-poor band thickness from baseline to end of treatment, measured by ultrasound	Baseline and Day 29
Changes in Total Skin Thickness	Change in total skin thickness measured by ultrasound at end of treatment (Day 29) and individual visits (Days 8, 15, and 22) compared to baseline	Baseline and Days 8, 15, 22, and 29.

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 l Archet 2, 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

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Study Registration Dates

First Submitted
2011-05-03

First Submitted that Met QC Criteria
2011-05-03

First Posted (Estimated)
2011-05-04

Results Reporting Dates

Results First Submitted
2015-11-13

Results First Submitted that Met QC Criteria
2016-01-26

Results First Posted (Estimated)
2016-02-24

Study Record Updates

Last Update Submitted that met QC Criteria
2016-07-13

Last Update Posted (Estimated)
2016-08-15

Last Verified
2016-07

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
Betamethasone
Betamethasone Valerate
Betamethasone 17,21 dipropionate
Betamethasone benzoate
Betamethasone sodium phosphate

Study Documents

No study documents available

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Go to the classic website

Record 1 of 1

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COMPLETED

Study to Assess the Immunogenicity and Safety of Etanercept Produced Using a Modified Process in Patients With Plaque Psoriasis

ClinicalTrials.gov ID **NCT02274792**

Sponsor Amgen

Information provided by Amgen (Responsible Party)

Last Update Posted 2016 12 29

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to learn more about the immune response to etanercept produced using a modified process in patients with plaque psoriasis.

Feedback

Detailed Description

This is a multicenter, open label, single arm phase 4 study in patients with plaque psoriasis who are etanercept naïve and who are not receiving methotrexate therapy. The study will consist of a screening period of up to 30 days, a 24 week treatment period and a 30 day follow up period for safety. Etanercept dosing will follow the recommended label dosing for patients with plaque psoriasis.

Official Title

A Single arm Study to Assess the Immunogenicity and Safety of Etanercept Produced Using a Modified Process in Subjects With Plaque Psoriasis

Conditions

Plaque Psoriasis

Intervention / Treatment

- Drug: Etanercept

Other Study ID Numbers

- 20101177

Study Start

2015 01

Primary Completion (Actual)

2015 11

Study Completion (Actual)

2015 11

Enrollment (Actual)

132

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)

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

Mobile, Alabama, United States, 36608
Research Site

California Locations

Bakersfield, California, United States, 93309
Research Site

Beverly Hills, California, United States,



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 is ≥ 18 years of age at time of screening.
- Subject is a candidate for systemic therapy or phototherapy in the opinion of the investigator.
- Subject has involved body surface area (BSA) ≥ 10%, static physician global assessment (sPGA) ≥ 3, and Psoriasis Area and Severity Index (PASI) ≥ 10 at screening and at baseline.
- Subject is naïve to etanercept.
- Subject is a candidate for treatment with etanercept in the opinion of the investigator in addition to the caring physicians intent to initiate treatment with etanercept, as applicable.
- Subject is able to self inject etanercept or have a designee who can do so.
- Subject has not used methotrexate within 4 weeks from the first dose of etanercept.
- Subject has a negative test for hepatitis B surface antigen, hepatitis B core antibody and hepatitis C antibody.
- Subject has no known history of active tuberculosis.
- Subject has a negative test for tuberculosis during screening
- Subject, if female and not at least 2 years postmenopausal or history of hysterectomy, bilateral salpingectomy, or bilateral oophorectomy, has a negative serum pregnancy test ≤ 4 weeks from starting etanercept and a negative urine pregnancy test at baseline (day 1).

Exclusion Criteria:

- Subject has active erythrodermic, pustular, guttate psoriasis, or medication induced psoriasis, or other skin conditions at the time of the screening visit (e.g., eczema) that would interfere with evaluations of the effect of investigational product on psoriasis.
- Subject has any uncontrolled, clinically significant systemic disease (e.g., renal failure, heart failure, hypertension, pulmonary or liver disease, diabetes, anemia).
- Myocardial infarction or unstable angina pectoris within the last year.
- 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, Merkel cell carcinoma, or history of cancer (other than fully resected and surgically cured cutaneous basal cell and squamous cell carcinoma) within 5 years before the first dose of etanercept. If malignancy occurred more than 5 years ago, documentation of disease free state since treatment is required.
- Known history of alcoholic hepatitis or immunodeficiency syndromes including human Immunodeficiency virus (HIV) infection.
- Subject has any active infection (including chronic or localized infections) for which anti infectives were indicated within 4 weeks prior to first dose of etanercept.

- Subject has a serious infection, defined as requiring hospitalization or intravenous (IV) anti infectives within 8 weeks prior to first dose of etanercept.
- Any condition that, in the opinion of the investigator, might cause this study to be detrimental to the subject.
- Subject has any condition that could, in the opinion of the investigator, compromise the subject s ability to give written consent and/or comply with the study procedures, such as a history of substance abuse or a psychiatric condition.

Ages Eligible for Study

18 Years to 125 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 : N/A
Interventional Model : Single Group Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Etanercept Participants received etanercept 50 mg subcutaneously twice a week (BIW) for 12 weeks followed by 50 mg once a week for an additional 12 weeks.	Drug: Etanercept • Etanercept produced using the serum free process (SFP)2 was supplied in a single-use 1 mL prefilled syringe for subcutaneous injection. • Other Names: ◦ Enbrel®

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With Positive Anti-etanercept Binding Antibody Response During the Study	Seroreactivity to etanercept was evaluated using a validated enzyme-linked immunosorbent assay (ELISA).	Blood samples were collected for anti-etanercept antibody analysis before the administration of etanercept at baseline (day 1) and at week 12 and week 24.

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With Positive Anti-etanercept Binding Antibody Response at Week 24		Week 24
Percentage of Participants With Positive Anti-etanercept Binding Antibody Response at Week 12		Week 12
Percentage of Participants With Positive Anti-etanercept Neutralizing Antibody Response at Week 24	Samples confirmed to be positive on the binding assay were subsequently tested in a non-cell based assay to determine neutralizing activity against etanercept.	Week 24
Percentage of Participants With Positive Anti-etanercept Neutralizing Antibody Response at Week 12	Samples confirmed to be positive on the binding assay were subsequently tested in a non-cell based assay to determine neutralizing activity against etanercept.	Week 12

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

2014-10-22

First Submitted that Met QC Criteria
2014-10-22

First Posted (Estimated)
2014-10-24

Results Reporting Dates

Results First Submitted
2016-11-02

Results First Submitted that Met QC Criteria
2016-11-02

Results First Posted (Estimated)
2016-12-29

Study Record Updates

Last Update Submitted that met QC Criteria
2016-11-02

Last Update Posted (Estimated)
2016-12-29

Last Verified
2016-10

More Information

Terms related to this study

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

Efficacy and Safety Study of Guselkumab in the Treatment of Participants With Moderate to Severe Plaque-Type Psoriasis

ClinicalTrials.gov ID NCT02905331

Sponsor Janssen Research & Development, LLC

Information provided by Janssen Research & Development, LLC (Responsible Party)

Last Update Posted 2018 10 23

Study Details Tab

Study Overview

Brief Summary

The purpose of the study is to evaluate the efficacy, safety, pharmacokinetics, immunogenicity, usability, and acceptability of guselkumab delivered using SelfDose device in participants with moderate to severe plaque type psoriasis.

Feedback

Official Title

A Phase 3, Multicenter, Randomized, Double blind Placebo controlled Study Evaluating the Efficacy and Safety of CNTO 1959 (Guselkumab) Delivered Via a SelfDose (TM) Device in the Treatment of Subjects With Moderate to Severe Plaque Type Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Guselkumab
- Drug: Placebo

Other Study ID Numbers

- CR108203
- CNTO1959PSO3006 (Other Identifier) (OTHER: Janssen Research & Development, LLC)
- 2016 002022 37 (EudraCT Number)

Study Start (Actual)

2017 02 28

Primary Completion (Actual)

2018 02 06

Study Completion (Actual)

2018 02 06

Enrollment (Actual)

78

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

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

Florida Locations

Ocala, Florida, United States, 34470
Renstar Medical Research

Illinois Locations

Rolling Meadows, Illinois, United States, 60008
Arlington Dermatology

Indiana 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:

- A woman of childbearing potential must have a negative urine pregnancy test (beta human chorionic gonadotropin) at screening and at Week 0
- Before randomization, a woman must be either: a) Not of childbearing potential: premenarchal; postmenopausal (greater than [>] 45 years of age with amenorrhea for at least 12 months or any age with amenorrhea for at least 6 months and a serum follicle stimulating hormone level (FSH) >40 International Units Per Liter [IU/L]); permanently sterile (example, tubal occlusion, hysterectomy, bilateral salpingectomy); or otherwise be incapable of pregnancy, b) Of childbearing potential and practicing a highly effective method of birth control, consistent with local regulations regarding the use of birth control methods for subjects participating in clinical studies: example, established use of oral, injected or implanted hormonal methods of contraception; placement of an intrauterine device (IUD) or intrauterine system (IUS); barrier methods: condom or occlusive cap (diaphragm or cervical/vault caps) plus spermicidal foam/gel/ film/cream/suppository (if available in their locale); male partner sterilization (the vasectomized partner should be the sole partner for that participant); true abstinence (when this is in line with the preferred and usual lifestyle of the participant)
- Agree not to receive a Bacillus Calmette Guerin (BCG) vaccination during the study, or within 12 months after the last administration of study drug
- Have a Psoriasis Area and Severity Index (PASI) greater than or equal to [>=] 12 at screening and at baseline
- Have an involved body surface area (BSA) >= 10 percent (%) at screening and at baseline

Exclusion Criteria:

- Has unstable cardiovascular disease, defined as a recent clinical deterioration (eg, unstable angina, rapid atrial fibrillation) in the last 3 months or a cardiac hospitalization within the last 3 months
- Has a history of lymphoproliferative disease, including lymphoma; a history of monoclonal gammopathy of undetermined significance (MGUS); or signs and symptoms suggestive of possible lymphoproliferative disease, such as lymphadenopathy or splenomegaly
- Has a transplanted organ (with exception of a corneal transplant >3 months before the first administration of study drug)
- Has a nonplaque form of psoriasis (example, erythrodermic, guttate, or pustular)
- Has received any anti tumor necrosis factor alpha (TNF alpha) biologic therapy within 3 months before the first administration 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 : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Group 1 (Guselkumab: Placebo) Participants will receive 100 milligram (mg) guselkumab administered as a 100 milligram per milliliter (mg/mL) solution in a single-use prefilled syringe (PFS) assembled in a SelfDose device at Weeks 0, 4, 12, 20, and 28; liquid placebo for guselkumab 100 mg at Week 16 to maintain the study blind.	Drug: Guselkumab • Participants will receive 100 mg of Guselkumab as 100 mg/mL solution via SelfDose device. • Other Names: ◦ CNTO 1959 Drug: Placebo • Participants will receive matching placebo supplied in a PFS assembled in a SelfDose device.
Experimental: Group 2 (Placebo: Guselkumab) Partcipants will receive placebo at Weeks 0, 4, and 12 followed by guselkumab 100 mg at Weeks 16, 20, and 28.	Drug: Guselkumab • Participants will receive 100 mg of Guselkumab as 100 mg/mL solution via SelfDose device. • Other Names: ◦ CNTO 1959 Drug: Placebo • Participants will receive matching placebo supplied in a PFS assembled in a SelfDose device.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Who Achieved an Investigator s Global Assessment (IGA) Score of Cleared (0) or Minimal (1) at Week 16	The IGA documents the investigator s assessment of the participants psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The participant s psoriasis is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Participants who achieved an IGA score of cleared (0) or minimal (1) were considered IGA cleared or minimal responders. Non-responder imputation (counted as non-responders) was applied for participants who met treatment failure rules, as well as for remaining missing data after treatment failure. Participants who discontinued study drug due to lack of efficacy, an adverse event (AE) of worsening of psoriasis, or who started a protocol-prohibited medication/therapy during study that could improve psoriasis were considered as treatment failures for the study.	Week 16
Percentage of Participants Who Achieved a Psoriasis Area and Severity Index (PASI) 90 Response at Week 16	The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas is assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90 percent (%) to 100% involvement), and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 (no psoriasis) to 72. A higher score indicates more severe disease. A PASI 90 response represents participants who achieved	Week 16

	at least a 90 percent improvement from baseline in the PASI score. Non-responder imputation (counted as non-responders) was applied for participants who met treatment failure rules, as well as for remaining missing data after treatment failure.	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Who Achieve an IGA Score of Cleared (0) at Week 16	The IGA documents the investigator s assessment of the participants psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The participant s psoriasis is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Participants who achieved an IGA score of cleared (0) were considered IGA cleared responders. Non-responder imputation (counted as non-responders) was applied for participants who met treatment failure rules, as well as for remaining missing data after treatment failure.	Week 16
Percentage of Participants Who Achieve a PASI 100 Response at Week 16	The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas is assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90% to 100% involvement), and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 (no	Week 16

	psoriasis) to 72. A higher score indicates more severe disease. Participants with 100% improvement in PASI from baseline (PASI score=0) were considered PASI 100 responders. Non-responder imputation (counted as non-responders) was applied for participants who met treatment failure rules, as well as for remaining missing data after treatment failure.	
Percentage of Participants Who Achieved an IGA Score of Mild or Better (Less Than or Equal to [<=] 2) at Week 16	The IGA documents the investigator s assessment of the participants psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The participant s psoriasis is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Participants who achieved an IGA score of cleared (0), minimal (1), or mild (2) were considered IGA mild or better responders. Non-responder imputation (counted as non-responders) was applied for participants who met treatment failure rules, as well as for remaining missing data after treatment failure.	Week 16
Percentage of Participants Who Achieve a PASI 50 Response and a PASI 75 Response at Week 16	The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas is assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90% to 100% involvement), and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 (no	Week 16

	psoriasis) to 72. A higher score indicates more severe disease. Participants with >=50% and >= 75% improvement in PASI from baseline were considered PASI 50 and PASI 75 responders respectively. Non-responder imputation (counted as non-responders) was applied for participants who met treatment failure rules, as well as for remaining missing data after treatment failure.	
Percent Improvement From Baseline in PASI Score at Week 16	The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas is assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90% to 100% involvement), and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 (no psoriasis) to 72. A higher score indicates more severe disease. Participants were analyzed according to the assigned treatment to which they were randomized, regardless of the treatment they actually received.	Baseline and Week 16
Percent Improvement From Baseline in PASI Score Through Week 40	The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas is assessed separately for the percentage of the area involved, which translates to a	Baseline, Week 4, 8, 12, 20, 24, 28, 32, and Week 40 (4 weeks beyond the recommended every 8 weeks

	numeric score that ranges from 0 (indicates no involvement) to 6 (90% to 100% involvement), and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 (no psoriasis) to 72. A higher score indicates more severe disease. Participants were analyzed according to the assigned treatment to which they were randomized, regardless of the treatment they actually received. From week 20, participants in placebo group, only included participants who crossed over to receive guselkumab at week 16.	[q8w] dosing interval)
Percentage of Participants Who Achieved an IGA Score of Cleared (0), Cleared (0) or Minimal (1) and Mild or Better (<=2) Through Week 40	The IGA documents the investigator s assessment of the participant s psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The participant s psoriasis is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Participants who achieved an IGA score of cleared (0) or minimal (1) were considered IGA cleared or minimal responders while those achieved an IGA score of cleared (0), minimal (1), or mild (2) were considered IGA mild or better responders. Participants were analyzed according to the assigned treatment to which they were randomized, regardless of the treatment they actually received. From week 20, participants in placebo group, only included participants who crossed over to receive guselkumab at week 16.	Week 4, 8, 12, 20, 24, 28, 32, and Week 40 (4 weeks beyond the recommended q8w dosing interval)
Percentage of Participants Who Achieved PASI 100	PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk,	Week 4, 8, 12, 16, 20, 24, 28, 32, and Week 40 (4 weeks

Responses, PASI 90 Responses, PASI 75 Responses, and PASI 50 Responses	upper extremities, and lower extremities. Each of these areas is assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90% to 100% involvement), and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. PASI produces a numeric score that can range from 0 (no psoriasis) to 72.Participants with >=50%, >= 75%, >=90% and >= 100% improvement in PASI from baseline were considered PASI 50, 75, 90 and PASI 100 responders, respectively. Participants were analyzed according to the assigned treatment to which they were randomized, regardless of the treatment they actually received. From week 20, participants in placebo group, only included participants who crossed over to receive guselkumab at week 16.	beyond the recommended q8w dosing interval)

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
2016-09-14

First Submitted that Met QC Criteria
2016-09-14

First Posted (Estimated)
2016-09-19

Results Reporting Dates

Results First Submitted
2018-08-09

Results First Submitted that Met QC Criteria
2018-08-09

Results First Posted
2018-09-06

Study Record Updates

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

Last Update Posted
2018-10-23

Last Verified
2018-09

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

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/31/NCT02905331/Prot_000.pdf) [PDF, 1.78MB, 2016 11 16]
- Statistical Analysis Plan (https://storage.googleapis.com/ctgov2 large docs/31/NCT02905331/SAP_001.pdf) [PDF, 0.76MB, 2017 05 17]

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

Evaluate Efficacy, and Safety of Topical Therapy and Etanercept in Subjects With Moderate to Severe Plaque Psoriasis

ClinicalTrials.gov ID NCT01235442

Sponsor Amgen

Information provided by Amgen (Responsible Party)

Last Update Posted 2018 08 07

Study Details Tab

Study Overview

Brief Summary

The primary hypothesis of this trial is that the addition of short courses of clobetasol propionate foam to etanercept monotherapy in subjects with moderate to severe plaque psoriasis will yield greater efficacy compared with etanercept monotherapy, as measured by PASI 75 at Week 12.

Feedback

Official Title

A Randomized Study to Evaluate the Efficacy and Safety of Adding Topical Therapy to Etanercept in Subjects With Moderate to Severe Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: 1=Etanercept
- Drug: 2=Clobetasol propionate foam

Other Study ID Numbers

- 20080470

Study Start

2010 09

Primary Completion (Actual)

2011 10

Study Completion (Actual)

2011 12

Enrollment (Actual)

592

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) 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:

- Subject has had stable moderate to severe plaque psoriasis for at least 6 months
- Subject has involved BSA ≥ 10% and PASI ≥ 10 at screening and at baseline.
- Subject is a candidate for systemic therapy or phototherapy in the opinion of the investigator

Exclusion Criteria:

- Subject has active guttate, erythrodermic, or pustular psoriasis at the time of the screening visit.
- Subject has evidence of skin conditions at the time of the screening visit (eg, eczema) that would interfere with evaluations of the effect of etanercept and/orclobetasol propionate foam on psoriasis.
- Subject diagnosed with medication induced or medication exacerbated psoriasis
- Subject has any active Common Toxicity Criteria (CTC) grade 2 or higher infection
- Subject has a significant concurrent medical condition or laboratory abnormalities as defined in the study protocol.
- Subject has used any of the following therapies within 14 days of the first dose: UVB therapy or topical psoriasis therapies other than Class I or II topical steroids.
- Subject has used any of the following therapies within 28 days of the first dose: Class I or II topical steriods, UVA therapy (with or without psoralen), or systemic psoriasis therapies
- Subject has used one or more biologic therapies (other than interleukin (IL)12/IL23 inhibitors) within 3 months of the first dose
- Subject has used an IL 12/IL 23 inhibitor within 6 months of the first dose of etanercept
- Subject has ever used efalizumab (Raptiva®).

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: etanercept and clobetasol Etanercept 50 mg twice weekly x 12 weeks + clobetasol propionate foam (weeks 11 and 12) then Etanercept 50 mg once weekly x 12 weeks + clobetasol propionate foam (weeks 23 and 24)	Drug: 2=Clobetasol propionate foam • 0.05% clobetasol propionate foam applied topically twice daily during two up-to-2 week courses
Experimental: etanercept Etanercept 50 mg twice weekly x 12 weeks then Etanercept 50 mg once weekly x 12 weeks	Drug: 1=Etanercept • 50 mg SC bi-weekly for 12 weeks followed by 50 mg SC weekly for 12 weeks.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
PASI 75 at Week 12	The percentage of participants with the Psoriasis Area and Severity Indexs (PASI) 75 responses at week 12. PASI is an assessment of psoriasis based on severity of erythema, infiltration, and desquamation as well as area of involvement. The PASI score ranges from 0 to 72. The higher score represents the worse symptom severity. A response was considered a 75% reduction in the PASI score from Baseline.	Week 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
sPGA (0,1) at Week 12	The percentage of participants achieving sPGA 0 or 1 at week 12. Static physician global assessment of psoriasis (sPGA) is a physician s global assessment of the participant s psoriasis based on severity of induration, scaling, and erythema. The sPGA of psoriasis comprises a 6-point scale ranging from 0 (clear) to 5 with increasing severity.	Week 12
PASI 90 at Week 12	The percentage of participants with the Psoriasis Area and Severity Indexs (PASI) 90 responses at week 12. PASI is an assessment of psoriasis based on severity of erythema, infiltration, and desquamation as well as area of involvement. The PASI score ranges from 0 to 72. The higher score represents the worse symptom severity. A	Week 12

	response was considered a 90% reduction in the PASI score from Baseline.	
Patient Satisfaction at Week 12	Patient assessment of treatment satisfaction status at week 12. It is a measure of a participant s level of satisfaction with the medication s control of psoriasis, ranging from "very satisfied" to "very dissatisfied."	Week 12
Percent PASI Improvement From Baseline at Week 12	The percentage of the improvement in PASI score at week 12 from baseline. PASI is an assessment of psoriasis based on severity of erythema, infiltration, and desquamation as well as area of involvement. The PASI score ranges from 0 to 72. The higher score represents the worse symptom severity.	Week 12
PASI 75 at Week 24	The percentage of participants with the Psoriasis Area and Severity Indexs (PASI) 75 responses at week 24. PASI is an assessment of psoriasis based on severity of erythema, infiltration, and desquamation as well as area of involvement. The PASI score ranges from 0 to 72. The higher score represents the worse symptom severity. A response was considered a 75% reduction in the PASI score from Baseline.	Week 24
sPGA (0,1) at Week 24	The percentage of participants achieving sPGA 0 or 1 at week 24. Static physician global assessment of psoriasis (sPGA) is a physician s global assessment of the participant s psoriasis based on severity of induration, scaling, and erythema. The sPGA of psoriasis comprises a 6-point scale ranging from 0 (clear) to 5 with increasing severity.	Week 24

Collaborators and Investigators

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

Sponsor

Amgen

Collaborators

- Wyeth is now a wholly owned subsidiary of Pfizer

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

- Lebwohl MG, Kircik L, Callis Duffin K, Pariser D, Hooper M, Wenkert D, Thompson EH, Yang J, Kricorian G, Koo J. A randomized study to evaluate the efficacy and safety of adding topical therapy to etanercept in patients with moderate to severe plaque psoriasis. J Am Acad Dermatol. 2013 Sep;69(3):385 92. doi: 10.1016/j.jaad.2013.03.031. Epub 2013 May 1. (https://pubmed.ncbi.nlm.nih.gov/23643256)

*** 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

2010-10-28

First Submitted that Met QC Criteria

2010-11-04

First Posted (Estimated)

2010-11-05

Results Reporting Dates

Results First Submitted

2013-05-15

Results First Submitted that Met QC Criteria

2013-08-27

Results First Posted (Estimated)

2013-10-31

Study Record Updates

Last Update Submitted that met QC Criteria

2018-07-09

Last Update Posted

2018-08-07

Last Verified

2015-08

More Information

Terms related to this study

Keywords Provided by Amgen

Psoriasis
Topical
etanercept
clobetasol propionate

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
Glucocorticoids
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Etanercept
Clobetasol

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

Pediatric Open-Label Extension Study of Etanercept in Patients With Plaque Psoriasis

ClinicalTrials.gov ID **NCT00141921**

Sponsor Amgen

Information provided by Amgen (Responsible Party)

Last Update Posted 2017 10 05

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to evaluate the long term safety and efficacy of etanercept in pediatric patients with moderate to severe psoriasis.

Feedback

Detailed Description

This study was a multicenter, open label extension study for pediatric patients who participated in Study 20030211 (NCT00078819).

Official Title

An Open Label Extension Study to Evaluate the Safety of Etanercept in Pediatric Subjects With Plaque Psoriasis

Conditions

Pediatric Plaque Psoriasis

Intervention / Treatment

- Drug: Etanercept

Other Study ID Numbers

- 20050111

Study Start (Actual)

2005 08 11

Primary Completion (Actual)

2011 12 19

Study Completion (Actual)

2017 08 16

Enrollment (Actual)

182

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: 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:

- Enrollment on previous Amgen study 20030211 (NCT00078819)

Exclusion Criteria:

- Serious or clinically significant adverse event on Amgen study 20030211 related to etanercept

Ages Eligible for Study

(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 : N/A
Interventional Model : Single Group Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Etanercept Participants received etanercept 0.8 mg/kg (up to a maximum dose of 50 mg) once weekly by subcutaneous injection for up to 264 weeks.	Drug: Etanercept • Open-label at a dose of 0.8 mg/kg (up to an intended dose of 50 mg) given once weekly by subcutaneous injection • Other Names: ◦ Enbrel®

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With Adverse Events	A serious adverse events is any AE that • is fatal • is life threatening • requires in-patient hospitalization or prolongation of existing hospitalization • results in persistent or significant disability/incapacity • is a congenital anomaly/birth defect • other significant medical hazard. The severity assessment for adverse events and infections (except injection site reactions) was done using the Common Toxicity Criteria (CTC) Version 2.0, where Grade 3 indicates a severe toxicity (incapacitating with inability to work or do usual activity).	264 Weeks

	An infectious event is an event that was considered by the investigator to be an infectious episode. An injection site reaction is a reaction at the site of the subcutaneous injection, commonly characterized, but not limited to symptoms of erythema (redness, usually raised), pruritis (itching), swelling, or pain that is persistent for 4 hours or longer.	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With Injection Site Reactions	An injection site reaction is a reaction at the site of the subcutaneous injection, commonly characterized, but not limited to symptoms of erythema (redness, usually raised), pruritis (itching), swelling, or pain that is persistent for 4 hours or longer.	264 weeks
Exposure-adjusted Adverse Event Rates	The exposure adjusted event rate for a given event in a given time period is defined as the number of events reported in the given time period divided by total patient-years on investigational product during the period. Exposure-adjusted event rate per 100 patient years = total number of events / patient years * 100. Multiple occurrences of the same event for a participant were counted as multiple events.	264 weeks
Number of Participants With Clinically Significant		264 weeks

Changes in Vital Signs		
Number of Participants With Grade 3 and 4 Laboratory Toxicities	The severity assessment for adverse events and infections (not including injection site reaction) used the Common Toxicity Criteria (CTC) Version 2.0, where Grade 1= Mild - aware of sign or symptom, but easily tolerated; Grade 2= Moderate - discomfort enough to cause interference with usual activity; Grade 3 = Severe - incapacitating with inability to work or do usual activity; Grade 4= Life-threatening - refers to an event in which the patient was, in the view of the investigator, at risk of immediate death at the time of event; Grade 5 = Fatal.	264 weeks
Number of Participants Who Developed Anti-etanercept Antibodies	Binding antibodies to etanercept were detected using an anti-etanercept immunoassay. The positive samples in the immunoassay were further analyzed for the presence of neutralizing antibodies using a bioassay. Participants who developed anti-etanercept antibodies are those who were antibody positive post-baseline with a negative or no result at baseline.	264 weeks
Percentage of Participants With a Psoriasis Area and Severity Index 50 Response (PASI 50)	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 0.0 to 72.0, with higher scores indicating	Baseline and weeks 12, 48, 96, 144, 192, 240 and 264

	greater severity and/or more extensive psoriasis.	
Percentage of Participants With a PASI 75 Response	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 0.0 to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis.	Baseline and weeks 12, 48, 96, 144, 192, 240 and 264
Percentage of Participants With a PASI 90 Response	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 0.0 to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis.	Baseline and weeks 12, 48, 96, 144, 192, 240 and 264
Percent Improvement From Study 20030211	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	Study 20030211 baseline, Study

Baseline in PASI Score	involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0.0 to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis. Percent improvement from baseline = (Baseline Value - Post-baseline Value) / Baseline Value * 100.	20050111 baseline and weeks 12, 48, 96, 144, 192, 240 and 264
Percentage of Participants With a Static Physicians Global Assessment (sPGA) of Clear (0) or Almost Clear (1)	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 12, 48, 96, 144, 192, 240 and 264
Percent Improvement From Study 20030211 Baseline in Childrens Dermatology Life Quality Index (CDLQI) Total Score	The Childrens Dermatology Life Quality Index (CDLQI) was used to assess the impact of psoriasis on subject health-related quality of life. The CDLQI has 10 items assessing health-related quality of life (HRQOL) in patients with skin disease each measured on a scale from 0 (Not at all) to 3 (Very much). The total score ranges from 0 to 30, with lower scores indicating better quality of life. If participants were ≥ 13 years old, the text instrument was completed by the participants themselves. Participants ≥ 8 but < 13 years old used the cartoon version of the instrument and participants ≤ 7 years old used the cartoon version of the instrument completed with help from the parents or caregivers.	Study 20030211 baseline, Study 20050111 baseline and weeks 24, 48, 72, 96, 120, 144, 168, 192, 216, 240 and 264

	Percent improvement from baseline = (Baseline Value - Post-baseline Value) / Baseline Value * 100.	
Percent Improvement From Study 20030211 Baseline in CDLQI Symptoms and Feelings Score	The Childrens Dermatology Life Quality Index (CDLQI) was used to assess the impact of psoriasis on subject health-related quality of life. The CDLQI has 10 items assessing health-related quality of life (HRQOL) in patients with skin disease each measured on a scale from 0 (not at all) to 3 (Very much). The CDLQI Symptoms and Feelings Score includes 2 questions and ranges from 0 to 6, with lower scores indicating better quality of life. Percent improvement from baseline = (Baseline Value - Post-baseline Value) / Baseline Value * 100.	Study 20030211 baseline, Study 20050111 baseline and weeks 24, 48, 72, 96, 120, 144, 168, 192, 216, 240 and 264
Percent Improvement From Study 20030211 Baseline in CDLQI Leisure Score	The Childrens Dermatology Life Quality Index (CDLQI) was used to assess the impact of psoriasis on subject health-related quality of life. The CDLQI has 10 items assessing health-related quality of life (HRQOL) in patients with skin disease each measured on a scale from 0 (not at all) to 3 (Very much). The CDLQI Leisure Score includes 3 questions and ranges from 0 to 9, with lower scores indicating better quality of life. Percent improvement from baseline = (Baseline Value - Post-baseline Value) / Baseline Value * 100.	Study 20030211 baseline, Study 20050111 baseline and weeks 24, 48, 72, 96, 120, 144, 168, 192, 216, 240 and 264
Percent Improvement From Study	The Childrens Dermatology Life Quality Index (CDLQI) was used to assess the impact of psoriasis on subject health-related quality of	Study 20030211 baseline,

20030211 Baseline in CDLQI School or Holidays Score	life. The CDLQI has 10 items assessing health-related quality of life (HRQOL) in patients with skin disease each measured on a scale from 0 (not at all) to 3 (Very much). The CDLQI School or Holidays Score includes 1 question (How much did your skin problem effect your school work/holiday plans over the last week?) and ranges from 0 to 3, with lower scores indicating better quality of life. Percent improvement from baseline = (Baseline Value - Post-baseline Value) / Baseline Value * 100.	Study 20050111 baseline and weeks 24, 48, 72, 96, 120, 144, 168, 192, 216, 240 and 264
Percent Improvement From Study 20030211 Baseline in CDLQI Personal Relationships Score	The Childrens Dermatology Life Quality Index (CDLQI) was used to assess the impact of psoriasis on subject health-related quality of life. The CDLQI has 10 items assessing health-related quality of life (HRQOL) in patients with skin disease each measured on a scale from 0 (not at all) to 3 (Very much). The CDLQI Personal Relationships Score includes 2 questions and ranges from 0 to 6, with lower scores indicating better quality of life. Percent improvement from baseline = (Baseline Value - Post-baseline Value) / Baseline Value * 100.	Study 20030211 baseline, Study 20050111 baseline and weeks 24, 48, 72, 96, 120, 144, 168, 192, 216, 240 and 264
Percent Improvement From Study 20030211 Baseline in CDLQI Sleep Score	The Childrens Dermatology Life Quality Index (CDLQI) was used to assess the impact of psoriasis on subject health-related quality of life. The CDLQI has 10 items assessing health-related quality of life (HRQOL) in patients with skin disease each measured on a scale from 0 (not at all) to 3 (Very much). The CDLQI Sleep Score includes 1 question (How much has your sleep been affected by your skin problems over	Study 20030211 baseline, Study 20050111 baseline and weeks 24, 48, 72, 96, 120, 144,

	the last week?) and ranges from 0 to 3, with lower scores indicating better quality of life. Percent improvement from baseline = (Baseline Value - Post-baseline Value) / Baseline Value * 100.	168, 192, 216, 240 and 264
Percent Improvement From Study 20030211 Baseline in CDLQI Treatment Satisfaction Score	The Childrens Dermatology Life Quality Index (CDLQI) was used to assess the impact of psoriasis on subject health-related quality of life. The CDLQI has 10 items assessing health-related quality of life (HRQOL) in patients with skin disease each measured on a scale from 0 (not at all) to 3 (Very much). The CDLQI Treatment Satisfaction Score includes 1 question (How much of a problem has the treatment for your skin been over the last week?) and ranges from 0 to 3, with lower scores indicating better quality of life. Percent improvement from baseline = (Baseline Value - Post-baseline Value) / Baseline Value * 100.	Study 20030211 baseline, Study 20050111 baseline and weeks 24, 48, 72, 96, 120, 144, 168, 192, 216, 240 and 264
Improvement From Study 20030211 Baseline in Joint Pain	Participants were asked to indicate how much joint pain they had experienced in the last 7 days on a visual analog scale (VAS) from no pain on the left end of the line (score = 0) to severe pain on the right side of the line (score = 10). Improvement from baseline = (Baseline Value - Post-baseline Value).	Study 20030211 baseline, Study 20050111 baseline and weeks 12, 24, 36, 48, 60, 72, 84, 96, 108, 120, 132, 144, 156, 168, 180, 192, 204,

		216, 228, 240, 252 and 264

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

- Paller AS, Siegfried EC, Eichenfield LF, Pariser D, Langley RG, Creamer K, Kricorian G. Long term etanercept in pediatric patients with plaque psoriasis. J Am Acad Dermatol. 2010 Nov;63(5):762 8. doi: 10.1016/j.jaad.2010.04.004. Epub 2010 Jun 3. (https://pubmed.ncbi.nlm.nih.gov/20605256)
- Paller AS, Siegfried EC, Pariser DM, Rice KC, Trivedi M, Iles J, Collier DH, Kricorian G, Langley RG. Long term safety and efficacy of etanercept in children and adolescents with plaque psoriasis. J Am Acad Dermatol. 2016 Feb;74(2):280 7.e1 3. doi: 10.1016/j.jaad.2015.09.056. (https://pubmed.ncbi.nlm.nih.gov/26775775)

*** 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
2005-08-31

First Submitted that Met QC Criteria
2005-08-31

First Posted (Estimated)
2005-09-02

Results Reporting Dates

Results First Submitted
2016-11-29

Results First Submitted that Met QC Criteria
2016-12-15

Results First Posted
2017-02-10

Study Record Updates

Last Update Submitted that met QC Criteria
2017-09-07

Last Update Posted
2017-10-05

Last Verified
2017-09

More Information

Terms related to this study

Keywords Provided by Amgen

Immunex
Amgen
Pediatric,
plaque psoriasis
clinical trial

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

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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 and Safety of Etanercept 50 mg Once Weekly Plus As Needed Topical Agent in Moderate to Severe Plaque Psoriasis (REFINE)

ClinicalTrials.gov ID NCT01313221

Sponsor Amgen

Information provided by Amgen (Responsible Party)

Last Update Posted 2017 03 15

Study Details Tab

Study Overview

Brief Summary

To estimate the difference in effectiveness between treatment with etanercept 50 mg twice weekly (BIW) and treatment with etanercept 50 mg once weekly (QW) plus an as needed (PRN) topical agent for 12 weeks in adults with moderate to severe plaque psoriasis.

Feedback

Detailed Description

The recommended starting dose of etanercept for adult plaque psoriasis patients is a 50 mg dose given twice a week (BIW) for 3 months followed by a reduction to a maintenance dose of 50 mg once weekly (QW). While most patients with moderate to severe plaque psoriasis are managed satisfactorily on etanercept monotherapy, a proportion may require a modified or alternative treatment regimen (eg, to handle flares or loss of effect) at some point during their chronic management. Despite the clinical need, no published data from randomized controlled studies are currently available that demonstrate efficacy and safety of combined etanercept based regimens in patients with plaque psoriasis.

The addition of an as needed topical medication to the step down dose of etanercept 50 mg once weekly administered after the initial 12 week period of 50 mg twice weekly may be a potential option for patients who may require adjunctive therapy. This study aimed to provide data on this treatment option by estimating the difference in mean percent change in Psoriasis Area and Severity Index (PASI) scores between step down etanercept 50 mg once weekly supplemented with as needed topical medication and continuous treatment with etanercept 50 mg twice weekly.

Eligible patients will be enrolled in the study and will receive etanercept 50 mg twice weekly for 12 weeks. After 12 weeks of etanercept treatment, participants will be randomized in a 1:1 ratio to 1 of 2 treatment groups.

Official Title

A Randomized, Blinded Assessor Study to Evaluate the Efficacy and Safety of Etanercept 50 mg Once Weekly Plus As Needed Topical Agent Versus Etanercept 50 mg Twice Weekly in Subjects With Moderate to Severe Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Biological: etanercept
- Drug: Topical agents

Other Study ID Numbers

- 20090647

Study Start

2011 04

Primary Completion (Actual)

2012 12

Study Completion (Actual)

2013 05

Enrollment (Actual)

310

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: 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.

Canada

Quebec, Canada, G1J 1X7
Research Site

Quebec, Canada, G1V 4X7
Research Site

Click to view interactive map

Alberta Locations

Calgary, Alberta, Canada, T2G 1B1
Research Site

British Columbia 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:

- Has had stable moderate to severe plaque psoriasis for at least 6 months (eg, no morphology changes or significant flares of disease activity in the opinion of the investigator).
- Has a body surface area (BSA) involvement ≥ 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.
- Other inclusion criteria may apply.

Exclusion Criteria:

- 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 etanercept on psoriasis.
- Diagnosed with medication induced or medication exacerbated psoriasis.
- Significant concurrent medical conditions.
- Has any active localized infection; requiring local intervention or chronic or localized infections.
- Other 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 : Single (Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Active Comparator: Etanercept 50 mg BIW Following 12 weeks of etanercept 50 mg twice weekly, participants were randomized to 50 mg etanercept twice weekly for 12 weeks.	Biological: etanercept • Administered by subcutaneous injection • Other Names: ◦ Enbrel
Experimental: Etanercept 50 mg QW + Topical Following 12 weeks of etanercept 50 mg twice weekly, participants were randomized to 50 mg etanercept once weekly plus as needed topical agents.	Biological: etanercept • Administered by subcutaneous injection • Other Names: ◦ Enbrel Drug: Topical agents • Topical agents prescribed at the discretion of the Principal Investigator and were are limited to the following: ◦ hydrocortisone 2.5% ◦ betamethasone valerate 0.1% ◦ betamethasone dipropionate 0.05% ◦ clobetasol 0.05% ◦ calcitriol ◦ calcipotriol plus betamethsone dipropionate 0.05%

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percent Change in Psoriasis Area and Severity Index (PASI) From Week 12 to Week 24	The Psoriasis Area and Severity Index (PASI) score is a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and desquamation (scaling) on a scale from none (0), mild (1), moderate (2), severe (3) or very severe (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. Change from Week 12 to Week 24 is presented as a percentage of the Week 12 value: Week 12 value - Week 24 value / Week 12 value * 100 so that a positive change indicates improvement. Change was adjusted for treatment using a mixed model.	Week 12 and Week 24

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percent Change in PASI From Week 12 to Weeks 16 and 20	The Psoriasis Area and Severity Index (PASI) score is a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and desquamation (scaling) on a scale from none (0), mild (1), moderate (2), severe (3) or very severe (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. Change from Week 12 presented as a percentage of the Week 12	Week 12, Week 16 and Week 20

	value: Week 12 value - postbaseline value / Week 12 value * 100, so that a positive change indicates improvement. Change was adjusted for treatment using a mixed model.	
Percent Change in PASI From Baseline to Weeks 12, 16, 20, and 24	The Psoriasis Area and Severity Index (PASI) score is a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and desquamation (scaling) on a scale from none (0), mild (1), moderate (2), severe (3) or very severe (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. Change from Baseline is presented as a percentage of the Baseline value: Baseline value - postbaseline value / Baseline value * 100, so that a positive change indicates improvement.	Baseline and Weeks 12, 16, 20, and 24
Percentage of Participants With a PASI 50 Response	The percentage of participants with a 50% reduction (improvement) in Psoriasis Area and Severity Index (PASI) score from Baseline. PASI score is based on an assessment of erythema (reddening), induration (plaque thickness), desquamation (scaling), and the percent area affected as observed on the day of examination. The score ranges from 0 (best outcome) to 72 (worst outcome).	Baseline and Weeks 12, 16, 20 and 24
Percentage of Participants With a PASI 75 Response	The percentage of participants with a 75% reduction (improvement) in Psoriasis Area and Severity Index (PASI) score from Baseline. PASI score is based on an assessment of erythema (reddening), induration (plaque thickness), desquamation (scaling), and the percent area affected as observed on the day of examination.	Baseline and Weeks 12, 16, 20 and 24

	The score ranges from 0 (best outcome) to 72 (worst outcome).	
Percentage of Participants With a PASI 90 Response	The percentage of participants with a 90% reduction (improvement) in Psoriasis Area and Severity Index (PASI) score from Baseline. PASI score is based on an assessment of erythema (reddening), induration (plaque thickness), desquamation (scaling), and the percent area affected as observed on the day of examination. The score ranges from 0 (best outcome) to 72 (worst outcome).	Baseline and Weeks 12, 16, 20 and 24
Percentage of Participants With a Static Physicians Global Assessment (sPGA) of Psoriasis Score of 0 (Clear) or 1 (Almost Clear)	The sPGA scale is completed by the same blinded assessor performing the PASI assessments and is designed to evaluate the physicians global assessment of the participants psoriasis based on severity of induration, scaling, and erythema. The sPGA is assessed on a scale of 0 to 5 (0 = clear, 5 = severe).	Weeks 12, 16, 20, and 24
Percent Change in the Percentage of Body Surface Area (BSA) Involvement From Week 12 to Weeks 16, 20, and 24	The percentage of body surface area involved with psoriasis was measured by the same blinded assessor performing the PASI assessments. Change from Week 12 is presented as a percentage of the Week 12 value: Week 12 value - postbaseline value / Week 12 value * 100, so that a positive change indicates improvement. Change was adjusted for treatment using a mixed model.	Weeks 12, 16, 20, and 24
Percent Change in the Percentage of	The percentage of body surface area involved with psoriasis was measured by the same	Baseline and Weeks

Body Surface Area (BSA) Involvement From Baseline to Weeks 12, 16, 20, and 24	blinded assessor performing the PASI assessments. Change from Baseline \ is presented as a percentage of the Baseline value: Baseline value - postbaseline value / Baseline value * 100, so that a positive change indicates improvement.	12, 16, 20, and 24
Change From Week 12 to Week 24 in Dermatology Quality of Life Index (DQLI) Total Score	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. Change from Week 12 to Week 24 is calculated as: Week 12 value - Week 24 value so that a positive change indicates improvement. Change was adjusted for treatment using a mixed model.	Week 12 and Week 24
Change From Baseline to Weeks 12 and 24 in Dermatology Quality of Life Index (DQLI) Total Score	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. Change from Baseline was calculated as Baseline value -	Baseline and Week 12 and Week 24

	postbaseline value so that a positive change indicates improvement.	
Change in Treatment Satisfaction Questionnaire for Medications (TSQM) Scores From Week 12 to Week 24	TSQM is a validated questionnaire consisting of 14 questions regarding a participant s perception of the level of satisfaction or dissatisfaction with the medication they are taking. Four scales are generated: side effects, effectiveness, convenience, and global satisfaction. Optional responses are: Extremely Dissatisfied, Very Dissatisfied, Dissatisfied, Somewhat Satisfied, Satisfied, Very Satisfied, and Extremely Satisfied. From the responses, a scale score from 0 - 100 is calculated, with a higher score indicating greater satisfaction. Change was calculated as Week 24 - Week 12 so that a positive change indicates improvement over time. Change was adjusted for treatment using a mixed model.	Week 12 and Week 24
Change in Treatment Satisfaction Questionnaire for Medications (TSQM) Scores From Baseline to Weeks 12 and 24	The TSQM is a validated questionnaire consisting of 14 questions regarding a participant s perception of the level of satisfaction or dissatisfaction with the medication they are taking. Four scales are generated: side effects, effectiveness, convenience, and global satisfaction. Optional responses are: Extremely Dissatisfied, Very Dissatisfied, Dissatisfied, Somewhat Satisfied, Satisfied, Very Satisfied, and Extremely Satisfied. From the responses, a scale score from 0 - 100 is calculated, with a higher score indicating greater satisfaction. Change was calculated as postbaseline value - Baseline value so that a positive change indicates improvement.	Baseline and Weeks 12 and 24
Health Resource Utilization: Number of Participants With Visits to a	Participants completed a questionnaire to assess their health resource utilization (HRU) related to psoriasis. To assess the number of visits to a healthcare provider, participants answered the following questions regarding the	Baseline and 24 weeks

Healthcare Provider	past 4 weeks: How many times have you been to any physicians office or urgent care clinic? How many times have you seen a nurse practitioner, a physician assistant, a psychologist, a naturopath, an acupuncturist, a chiropractor, or other healthcare professional (HCP)? The number of participants with one or more visits is reported.	
Health Resource Utilization: Number of Participants With Home Healthcare Visits	Participants completed a questionnaire to assess their health resource utilization (HRU) related to psoriasis. To assess the number of homecare visits, participants answered the following question regarding the past 4 weeks: How many times have you received care from a health professional in your home? The number of participants with one or more visits is reported.	Baseline and 24 weeks
Health Resource Utilization: Number of Participants Requiring Paid Help With Chores	Participants completed a questionnaire to assess their health resource utilization (HRU) related to psoriasis. To assess the number of participants who needed paid help with chores, participants answered the following question regarding the past 4 weeks: How many times have you paid someone to help you do chores around the house (cleaning, maintenance, lawn care)? The number of participants who paid for help one or more times is reported.	Baseline and 24 weeks
Health Resource Utilization: Number of Participants Who Needed Friend or Family Care	Participants completed a questionnaire to assess their health resource utilization (HRU) related to psoriasis. Participants answered the following question regarding the past 4 weeks: How many hours have you had a friend or family member take time off work to provide care or transportation? The number of participants who had paid or non-paid help for one or more hours is reported.	Baseline and 24 weeks
Health Resource Utilization: Out	Participants completed a questionnaire to assess their health resource utilization (HRU)	Baseline and 24

of Pocket Expenses	related to psoriasis. To assess out of pocket expenses, participants answered the following question regarding the past 4 weeks: Not counting study mandated visits, what out-of-pocket expenses did you spend for the management of psoriasis (i.e. costs due to travelling to doctor appointment, hospital or clinic parking costs, alternative medications)?	weeks
Health Resource Utilization: Employment Status	Participants completed a questionnaire to assess their health resource utilization (HRU) related to psoriasis. Participants were asked their employment status at Baseline and at Week 24.	Baseline and 24 weeks
Health Resource Utilization: Productivity While Working	Participants who were employed were asked: How much did your psoriasis affect your productivity while you were working? Possible responses were: a) A great deal; b) Quite a bit; c) Somewhat; d) Minimally; e) Not at all.	Baseline and 24 weeks
Health Resource Utilization: Number of Participants With Missed Hours From Work	Participants who were employed answered the following question regarding the past 4 weeks: How many hours per week did you miss from work because of your psoriasis? The number of participants with one or more missed hours of work per week is reported.	Baseline and 24 weeks
Health Resource Utilization: Ability to Perform Daily Activities	Participants were asked: How much did your psoriasis affect your ability to do your daily activities or household chores? Possible answers were: a) A great deal; b) Quite a bit; c) Somewhat; d) Minimally; e) Not at all.	Baseline and 24 weeks
Number of Participants With Adverse Events	An adverse event (AE) is defined as any untoward medical occurrence in a clinical trial participant. A serious adverse event is defined as an adverse event that meets at least 1 of the following serious criteria: • fatal, • life	32 weeks

	threatening, • requires in-patient hospitalization or prolongation of existing hospitalization, • results in persistent or significant disability/incapacity, • congenital anomaly/birth defect, and/or • other significant medical hazard.	

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

- Papp KA, Barber K, Bissonnette R, Bourcier M, Lynde CW, Poulin Y, Shelton J, Garces K, Toole J, Poulin Costello M. Improvements in patient reported outcomes in patients with psoriasis receiving etanercept plus topical therapies: results from REFINE. J Eur Acad Dermatol Venereol. 2015 Aug;29(8):1555 61. doi: 10.1111/jdv.12934. Epub 2015 Jan 21. (https://pubmed.ncbi.nlm.nih.gov/25611084)
- Papp KA, Barber K, Bissonnette R, Bourcier M, Lynde CW, Poulin Y, Shelton J, Toole J, Vieira A, Poulin Costello M. A Randomized, blinded assessor study to Evaluate the efFIcacy and safety of etanercept 50 mg once weekly plus as Needed topical agent vs. Etanercept 50 mg twice weekly in patients with moderate to severe plaque psoriasis (REFINE). J Eur Acad Dermatol Venereol. 2015 Feb;29(2):361 366. doi: 10.1111/jdv.12555. Epub 2014 Jul 1. (https://pubmed.ncbi.nlm.nih.gov/24980988)

- Gooderham MJ, Poulin Costello M, Shelton J, Bayan N, Papp KA. Predictors of Topical Use in Psoriasis Patients in the REFINE Study. J Cutan Med Surg. 2016 Mar Apr;20(2):106 12. doi: 10.1177/1203475415604322. Epub 2015 Sep 1. (https://pubmed.ncbi.nlm.nih.gov/26330052).

*** 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
2011-02-24

First Submitted that Met QC Criteria
2011-03-10

First Posted (Estimated)
2011-03-11

Results Reporting Dates

Results First Submitted
2013-12-10

Results First Submitted that Met QC Criteria
2014-03-31

Results First Posted (Estimated)
2014-05-02

Study Record Updates

Last Update Submitted that met QC Criteria
2017-02-07

Last Update Posted

2017-03-15

Last Verified

2017-02

More Information

Terms related to this study

Keywords Provided by Amgen

plaque psoriasis
moderate
severe
etanercept
Enbrel
topical

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

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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).

COMPLETED

Trial of IMO-3100 in Patients With Moderate to Severe Plaque Psoriasis

ClinicalTrials.gov ID **NCT01622348**

Sponsor Idera Pharmaceuticals, Inc.

Information provided by Idera Pharmaceuticals, Inc. (Responsible Party)

Last Update Posted 2018 01 09

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to evaluate different dose levels of IMO 3100 compared to placebo administered for 4 weeks to patients with moderate to severe plaque psoriasis.

Detailed Description

Feedback

To evaluate the safety, tolerability and treatment effect of different dose levels of IMO 3100 compared to placebo administered for 4 weeks to patients with moderate to severe plaque psoriasis.

Official Title

A Randomized, Double Blind, Placebo Controlled, 4 week Trial of IMO 3100 in Patients With Moderate to Severe Plaque Psoriasis

Conditions

Actively Extending Plaque Psoriasis | Moderate to Severe Plaque Psoriasis

Intervention / Treatment

- Drug: IMO 3100 at 0.16 mg/kg
- Drug: Saline for Injection
- Drug: IMO 3100 at 0.32 mg/kg

Other Study ID Numbers

- 3100 202

Study Start

2012 05

Primary Completion (Actual)

2012 11

Study Completion (Actual)

2012 12

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)

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

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

Florida Locations

Jacksonville, Florida, United States, 32204
Florida Center for Dermatology, P.A

Georgia Locations

Alpharetta, Georgia, United States, 30022
Atlanta Dermatology, Vein & Research Center, PC

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:

- Is age 18 to 70 years, inclusive;
- Completes the informed consent procedure (see Section 15.3), including signing and dating the informed consent form;
- Has moderate to severe plaque psoriasis meeting the criteria specified above;
- Female subjects must have a negative pregnancy test at screening and on Day 1 prior to start of treatment;
- Female subjects of childbearing potential (see Section 8.4.1) and male subjects who have partners of childbearing potential must agree to use effective birth control (contraception; see Section 8.4.1) from Screening through the treatment period and for four (4) weeks after the last injection of study drug.

Exclusion Criteria:

- Has known hypersensitivity to any oligodeoxynucleotide;
- Is nursing;
- Has body weight < 50 kg;
- Has BMI > 34.9 kg/m2;
- Regularly consumes > 3 drinks of alcoholic beverages (beer, wine, or distilled spirits) per day;
- Has a positive test for antibody to human immunodeficiency virus (HIV 1 or 2) or hepatitis C virus;
- Has a positive test for hepatitis B surface antigen (HBsAg);
- Has at screening safety laboratory tests meeting one or more of the following criteria:
- hemoglobin < 10.5 g/dL
- white blood cell count < 4,000 cells/mm3
- absolute neutrophil count (ANC) < 1500/mm3
- platelet count < 100,000/mm3
- alanine transaminase (ALT; SGPT) > 1.5x ULN
- aspartate transaminase (AST; SGOT) > 1.5x ULN
- serum total bilirubin > 1.4x ULN
- serum creatinine > 1.3x ULN;
- Has a history of allogeneic organ transplant (including bone marrow or stem cells);
- Has, within the past 10 years, had evidence of or required treatment for cancer (except treated basal or squamous cell carcinoma of the skin or cured cervical carcinoma in situ);
- Has had within the past three months or is expected to have during the study period any of the following treatments:
- surgery requiring general anesthesia
- hematopoietic stimulating agents (e.g., erythropoietin, G CSF, GM CSF)
- another investigational drug;
- Has other significant medical disease (chronic or active within the past 6 months), including, but not limited to: cardiac disease (e.g., unstable angina, myocardial

infarction, congestive heart failure, ventricular arrhythmia); uncontrolled seizure disorder; liver disease; chronic infection (e.g., tuberculosis); uncontrolled diabetes;
- Has any other condition that would, in the opinion of the Investigator, potentially compromise the safety or compliance of the patient or may preclude the patient s successful completion of the clinical trial.

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

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Placebo Comparator: Placebo Saline for Injection	Drug: Saline for Injection • Saline for Injection 0.01 mL/kg SC q wk x 4 wk based on body weight at screening, not to exceed 1.25 mL
Active Comparator: IMO-3100 at 0.16 mg/kg IMO-3100 at 0.16 mg/kg SC once weekly based on body weight at screening, not to exceed 20 mg per injection	Drug: IMO-3100 at 0.16 mg/kg • IMO-3100 at 0.16 mg/kg SC q wk x 4 wks based on body weight at screening, not to exceed 20 mg per injection
Active Comparator: IMO-3100 at 0.32 mg/kg IMO-3100 at 0.32 mg/kg SC q wk x 4 wk based on body weight at screening, not to exceed 40 mg per injection	Drug: IMO-3100 at 0.32 mg/kg • IMO-3100 at 0.32 mg/kg SC q wk x 4 wks based on body weight at screening, not to exceed 40 mg per injection

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Mean Epidermal Thickness at End-of-Treatment (EOT) Compared to Pre-treatment	The change from pre-treatment baseline to End-of-Treatment (EOT) in the epidermal thickness of the index lesion	8 weeks

Collaborators and Investigators

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

Sponsor

Idera Pharmaceuticals, Inc.

Collaborators

No information provided

Investigators

- Study Director: Robert D Arbeit, MD, Idera Pharmaceuticals, 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

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Study Registration Dates

First Submitted
2012-05-21

First Submitted that Met QC Criteria
2012-06-14

First Posted (Estimated)
2012-06-19

Results Reporting Dates

Results First Submitted
2017-10-12

Results First Submitted that Met QC Criteria
2017-10-12

Results First Posted
2017-11-13

Study Record Updates

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

Last Update Posted
2018-01-09

Last Verified
2017-12

More Information

Terms related to this study

Keywords Provided by Idera Pharmaceuticals, Inc.

Psoriasis
Plaque Psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

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Record 1 of 1

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COMPLETED

A Psoriasis Plaque Test Trial With LEO 90100 Compared to Betesil® in Patients With Psoriasis Vulgaris

ClinicalTrials.gov ID **NCT02518048**

Sponsor LEO Pharma

Information provided by LEO Pharma (Responsible Party)

Last Update Posted 2017 06 01

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to evaluate the anti psoriatic effect of LEO 90100 aerosol foam compared with Betesil® medicated plaster

Feedback

Detailed Description

The products will be applied on 6 test sites (each product on 3 test sites) once daily 6 days a week (except Sundays) for 4 weeks. The application sites for each product will be determined according to random assignment. Depending on the size of the psoriasis plaques, 2 or 4 test sites will be located within the same plaque; the treatment assignment will be done pair wise.

Official Title

A Phase 2a Trial Evaluating the Anti psoriatic Effect of LEO 90100 Aerosol Foam Compared to Betesil® Medicated Plaster in the Treatment of Psoriasis Vulgaris

Conditions

Skin and Connective Tissue Diseases

Intervention / Treatment

- Drug: LEO 90100 Aerosol foam
- Drug: Betesil® 2.25 mg

Other Study ID Numbers

- LP0053 1227

Study Start

2015 08

Primary Completion (Actual)

2016 01

Study Completion (Actual)

2016 01

Enrollment (Actual)

35

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.

France

Nice, France, 06000
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:

- Signed and dated informed consent has been obtained
- Subjects with a diagnosis of psoriasis vulgaris with preferably three lesions (plaques) located on arms, legs and/or trunk or at least two lesions (plaques) located on arms, legs and/or trunk. For subjects with three lesions, each lesion must have a size suitable to accommodate 2 test sites (test site area 5 cm2, distance between two test sites at least 2 cm). For subjects with two lesions, one lesion must have a size suitable to accommodate 4 test sites, and the other lesion must accommodate 2 test sites.
- Age 18 years or above
- Outpatients
- Female subjects must be of either
    - non childbearing potential, i.e. post menopausal or have a confirmed clinical history of sterility (e.g. the subject is without a uterus or has tubal ligation) or,
    - child bearing potential provided there is a confirmed negative pregnancy test prior to trial treatment to rule out pregnancy.

Exclusion Criteria:

- Female subjects who are breast feeding
- Systemic treatment with biological therapies, whether marketed or not, with a possible effect on psoriasis vulgaris within the following time periods prior to randomisation:
    - Etanercept within 4 weeks prior to randomisation and during the trial
    - Adalimumab, infliximab within 8 weeks prior to randomisation and during the trial
    - Ustekinumab within 16 weeks prior to randomisation and during the trial
    - Other products within 4 weeks/5 half lives prior to randomisation and during the trial (whichever is longer)
- Systemic treatment 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 trial
- Subjects using phototherapy within the following time periods prior to randomisation and during the trial:
    - PUVA: 4 weeks
    - UVB: 2 weeks
- Subjects using one of the following topical drugs for the treatment of psoriasis within the 4 week period prior to randomisation and during the trial:
    - Potent or very potent (WHO group III IV) corticosteroids
- Subjects using one of the following topical drugs for the treatment of psoriasis within 2 weeks prior to randomisation and during the trial:
    - 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), Tar products, Salicylic acid
- Subjects using emollients on the selected plaques within 1 week before randomisation and during the trial
- Initiation of, or expected changes to concomitant medication that may affect psoriasis vulgaris (e.g., beta blockers, antimalarial drugs, lithium and ACE inhibitors) within 2 weeks prior to the randomisation and during the trial
- Subjects with current diagnosis of guttate, erythrodermic, exfoliative or pustular psoriasis

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 : Single Group Assignment
Masking : Single (Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Active Comparator: LEO 90100 Aerosol foam Calcipotriol (as monohydrate) 50 mcg/g and betamethasone (as dipropionate) 0.5 mg/g (LEO 90100 Aerosol foam)	Drug: LEO 90100 Aerosol foam
Active Comparator: Betesil® 2.25 mg Betamethasone (as valerate). Each 7.5 cm x 10 cm medicated plaster contains: 2.250 mg of betamethasone valerate (corresponding to 1.845 mg of betamethasone). (Betesil®)	Drug: Betesil® 2.25 mg

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Absolute Change in Total Clinical Score (TCS) of Clinical Signs (Sum of Erythema, Scaling, Infiltration) Absolute Change in Total Clinical Score (TCS) of Clinical Signs (Sum of Erythema, Scaling, and Infiltration) at End of Treatment Compared to Baseline	The investigator assessed the severity of the clinical signs erythema, scaling, and infiltration for each test site by using a 7-point scale with half-mark values from 0 (no evidence) to 3.0 (severe). The total TCS was calculated for each test site by summing the scores for erythema, scaling, and infiltration for that particular test site. Each test site was assessed at Baseline and on Days 4, 8, 11, 15, 18, 22, 25, and 29 (EoT). The mean TCS at Baseline was 6.6 for both groups.	Day 1 (Baseline) to Day 29

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change in TCS at Individual Visits		Day 1 (Baseline) to Day 29
Change in Score of Erythema, Scaling, and Infiltration at Individual Visits	The investigator assessed the severity of the clinical signs erythema, scaling, and infiltration for each test site by using a 7-point scale with half-mark values from 0 (no evidence) to 3.0 (severe). Erythema: 0 (no evidence - normal skin color) to 3 (severe - intense red). Scaling: 0 (no evidence - no scaling) to 3 (severe - coarse, thick scales).	Day 1 (Baseline) to Day 29

	Infiltration: 0 (no evidence - no infiltration) to 3 (severe - very marked infiltration).	
Change in Total Skin Thickness and Echo-poor Band Thickness From Baseline to EoT	Skin thickness ultrasound measurements of the test sites were performed at Baseline and End of Treatment. Two skin parameters were calculated using ultrasound: • The mean total skin thickness • The mean echo-poor band thickness	Baseline to End of Treatment

Collaborators and Investigators

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

Sponsor

LEO Pharma

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
2015-08-05

First Submitted that Met QC Criteria
2015-08-06

First Posted (Estimated)
2015-08-07

Results Reporting Dates

Results First Submitted
2016-11-28

Results First Submitted that Met QC Criteria
2017-03-10

Results First Posted
2017-04-21

Study Record Updates

Last Update Submitted that met QC Criteria
2017-05-01

Last Update Posted
2017-06-01

Last Verified
2017-05

More Information

Terms related to this study

Keywords Provided by LEO Pharma

Psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Connective Tissue Diseases

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

Study to Compare U0267 Against Vehicle in Subjects With Plaque-type Psoriasis One of Two Phase 3 Studies

ClinicalTrials.gov ID **NCT00688519**

Sponsor Stiefel, a GSK Company

Information provided by GlaxoSmithKline (Stiefel, a GSK Company) (Responsible Party)

Last Update Posted 2017 01 02

Study Details Tab

Study Overview

Brief Summary

The purpose of the study is to demonstrate the safety and efficacy of U0267 in subjects with plaque type psoriasis.

Feedback

Official Title

A Multicenter, Randomized, Double Blind, Phase 3 Study of the Safety and Efficacy of Emulsion Formulation U0267, Versus Vehicle in Subjects With Plaque type Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: U0267
- Drug: Vehicle

Other Study ID Numbers

- 114741
- U0267 301 (Other Identifier) (OTHER: Stiefel)

Study Start

2008 03

Primary Completion (Actual)

2008 12

Study Completion (Actual)

2008 12

Enrollment (Actual)

336

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)

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 Center, Inc.

Colorado Locations

Denver, Colorado, United States, 80209
Cherry Creek Research, Inc.

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:

- Male or female subjects at least 12 years old and in good general health.
- Mild to moderate plaque type psoriasis

Exclusion Criteria:

- Known allergy or other adverse reaction to calcipotriene or other vitamin D analogs; or to any component of the investigational formulations
- History of hypercalcemia or of vitamin D toxicity.
- Diagnosis of generalized pustular or erythrodermic exfoliative psoriasis.
- Other serious skin disorder or any chronic medical condition that is not well controlled.
- Use of non biologic systemic anti psoriatic therapy or biologic therapy within four weeks of enrollment.
- Use of topical therapies that have a known beneficial effect on psoriasis, within 2 weeks of enrollment.
- Systemic medications for other medical conditions that are known to affect psoriasis within the past four weeks of enrollment.
- Use of any investigational therapy within 4 weeks of enrollment.
- Pregnant women, women who are breast feeding, or sexually active women of child bearing potential who are not practicing an acceptable method of birth control.

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 : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: U0267 Foam U0267 is a vitamin D3 analog (calcipotriene) foam. It is applied twice a day for 8 weeks to psoriasis lesions on the body.	Drug: U0267 • All treatments will be administered topically twice daily (morning and evening) for 8 weeks to areas affected with psoriasis (excluding face and scalp).
Placebo Comparator: Vehicle foam Vehicle foam is the same as the U0267 foam except that it does not have the active ingredient. It is applied twice a day for 8 weeks to psoriasis lesions on the body.	Drug: Vehicle • All treatments will be administered topically twice daily (morning and evening) for 8 weeks to areas affected with psoriasis (excluding face and scalp).

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Subjects With Treatment Success, Assessed Per the Investigator s Static Global Assessment (ISGA)	Assessment (on a scale of 0 to 4) was made as a visual average of all lesions, except those on the face/scalp. 0=clear; minor residual discoloration; no erythema/scaling/plaque thickness (PT). 1=almost clear; occasional fine scale/faint erythema/barely perceptible PT. 2=mild; fine scales predominate; light red coloration/mild PT. 3=moderate; coarse scales predominate; moderate red coloration/moderate PT. 4=severe; thick tenacious scale predominates; deep red coloration/severe PT. Treatment success=ISGA score 0 or 1, and a minimum improvement in the ISGA score of 2 grades from BL to week 8.	8 weeks

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Subjects With a Target Lesion Score of 0 or 1 for Erythema and at Least a 2-grade Improvement From Baseline at Week 8	Erythema was assessed on a 6-point scale. 0=no evidence of erythema; hyperpigmentation may be present. 1=faint erythema. 2=light red coloration. 3=moderate red coloration. 4=bright red coloration. 5=dusky to deep red coloration.	8 weeks
Number of Subjects With a Target Lesion Score of 0 or 1 for Scaling and	Scaling was assessed on a 6-point scale. 0=no evidence of scaling. 1=minimal; occasional fine scale over less than 5% of the lesion. 2=mild, fine scales predominate. 3=moderate; course scales predominate. 4=marked; thick non-tenacious	8 weeks

at Least a 2 Grade Improvement From Baseline at Week 8	scale predominates. 5=severe; very thick tenacious scale predominates.	
Number of Subjects With a Target Lesion Score of 0 for Plaque Thickness at Week 8	Plaque thickness was assessed on a 6-point scale. 0=no evidence of plaque thickness. 1=barely perceptible plaque thickness, approximately 0.5 millimeters (mm). 2=mild plaque thickness, approximately 1 mm. 3=moderate plaque thickness, approximately 1.5 mm. 4=marked plaque thickness, approximately 2 mm. 5=severe plaque thickness, approximately 2.5 mm or more.	8 weeks
Number of Subjects Who Have an ISGA Score of 0 or 1 at Week 8	Assessment (on a scale of 0 to 4) was made as a visual average of all lesions, except those on the face/scalp. 0=clear; minor residual discoloration; no erythema/scaling/plaque thickness (PT). 1=almost clear; occasional fine scale/faint erythema/barely perceptible PT. 2=mild; fine scales predominate; light red coloration/mild PT. 3=moderate; coarse scales predominate; moderate red coloration/moderate PT. 4=severe; thick tenacious scale predominates; deep red coloration/severe PT.	8 weeks
Number of Subjects Who Have Treatment Success at Week 8 Analyzed by Baseline ISGA (Mild or Moderate)	Assessment (on a scale of 0 to 4) was made as a visual average of all lesions, except those on the face/scalp. 0=clear; minor residual discoloration; no erythema/scaling/plaque thickness (PT). 1=almost clear; occasional fine scale/faint erythema/barely perceptible PT. 2=mild; fine scales predominate; light red coloration/mild PT. 3=moderate; coarse scales predominate; moderate red coloration/moderate PT. 4=severe; thick tenacious scale predominates; deep red coloration/severe PT. Treatment success=ISGA score 0 or 1, and a	8 weeks

	minimum improvement in the ISGA score of 2 grades from BL to week 8.	

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
2008-05-29

First Submitted that Met QC Criteria
2008-06-02

First Posted (Estimated)
2008-06-03

Results Reporting Dates

Results First Submitted
2010-11-05

Results First Submitted that Met QC Criteria
2010-11-05

Results First Posted (Estimated)
2010-12-08

Study Record Updates

Last Update Submitted that met QC Criteria
2016-11-15

Last Update Posted (Estimated)
2017-01-02

Last Verified
2016-11

More Information

Terms related to this study

Keywords Provided by GlaxoSmithKline (Stiefel, a GSK Company)

Plaque type Psoriasis
Psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Yes

IPD Plan Description

Patient level data for this study will be made available through www.clinicalstudydatarequest.com following the timelines and process described on this site.

Study Data/Documents

1. Study Protocol (https://www.clinicalstudydatarequest.com)

   Information Identifier

   114741

   Information Comments

   For additional information about this study please refer to the GSK Clinical Study Register

2. Annotated Case Report Form (https://www.clinicalstudydatarequest.com)

   Information Identifier

   114741

   Information Comments

   For additional information about this study please refer to the GSK Clinical Study Register

3. Statistical Analysis Plan (https://www.clinicalstudydatarequest.com)

   Information Identifier

   114741

   Information Comments

   For additional information about this study please refer to the GSK Clinical Study Register

4. Individual Participant Data Set (https://www.clinicalstudydatarequest.com)

Information Identifier

114741

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

5. Informed Consent Form (https://www.clinicalstudydatarequest.com)

Information Identifier

114741

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

6. Dataset Specification (https://www.clinicalstudydatarequest.com)

Information Identifier

114741

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

7. Clinical Study Report (https://www.clinicalstudydatarequest.com)

Information Identifier

114741

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by GlaxoSmithKline (Stiefel, a GSK Company)

Researchers can use this site to request access to anonymised patient level data and/or supporting documents from clinical studies to conduct further research. (https://www.clinicalstudydatarequest.com)

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Record 1 of 1

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COMPLETED

A Plaque Test Study With LEO 35299 in Psoriasis Vulgaris

ClinicalTrials.gov ID **NCT01580488**

Sponsor LEO Pharma

Information provided by LEO Pharma (Responsible Party)

Last Update Posted 2013 12 30

Study Details Tab

Study Overview

Brief Summary

The purpose of the study is to evaluate the anti psoriatic effect of LEO 35299 in different formulations, compared to Daivonex® ointment and Daivonex® ointment vehicle, using the psoriasis plaque test modified from the method developed by KJ Dumas and JR Scholtz.

Feedback

Official Title

A Plaque Test Study With LEO 35299 in Psoriasis Vulgaris

Conditions

Psoriasis Vulgaris

Intervention / Treatment

- Drug: B LEO 35299 20 mg/g cream
- Drug: C LEO 35299 20 mg/g cream
- Drug: E LEO 35299 10 mg/g solution
- Drug: F LEO 35299 10 mg/g solution
- Drug: Daivonex® ointment
- Drug: Daivonex® ointment vehicle

Other Study ID Numbers

- PLQ 008
- 2011 005349 11 (EudraCT Number)

Study Start

2012 04

Primary Completion (Actual)

2012 06

Study Completion (Actual)

2012 06

Enrollment (Actual)

24

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://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) - Hôpital l'Archet 2, 151 route Saint-Antoine de Ginestière

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 must provide signed and dated informed consent before any study related activities are carried out.
2. Age 18 years or above.
3. Males, or females of non child bearing potential.
4. Subjects with, in the opinion of the investigator, stable psoriasis based on Total Plaque Score evaluated at screening visit and at visit 2 (Baseline).

Exclusion Criteria:

1. Male subjects who are not willing to use a local contraception (such as condom) from the time of study entry and for three months following the last study drug application.
2. Female subjects who are pregnant, of child bearing potential or who are breast feeding.
3. 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 islonger) for experimental biological products prior to randomisation and during the study.
4. Systemic treatments with all other therapies than biologicals, with a potential effect on psoriasis vulgaris (e.g., corticosteroids, retinoids, immune suppressants) within the 4 week period prior to randomisation and during the study.
5. Subjects using one of the following topical drugs for the treatment of psoriasis within the 4 week period prior to randomisation and during the study:

   Potent or very potent (WHO group III IV) corticosteroids.
6. Subjects using of phototherapy within the following time periods prior to randomisation and during the study:
   - PUVA (4 weeks)
   - UVB (2 weeks)
7. Subjects using one of the following topical drugs for the treatment of psoriasis within two 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. macrolides)
   - Anthracen derivatives
   - Tar,
   - Salicylic acid.
8. Subjects with current diagnosis of guttate, erythrodermic, exfoliative or pustular psoriasis
9. Subjects with known/suspected disorders of calcium metabolism associated with hypercalcemia within the last 10 years, based on medical history and/or subject

interview

10. 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)
11. Subjects with current participation in any other interventional clinical, based on interview of the subject

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 : N/A
Interventional Model : Single Group Assignment
Masking : Single (Investigator)

Arms and Interventions

Intervention/Treatment
Drug: B LEO 35299 20 mg/g cream • once daily application, 3 weeks Drug: C LEO 35299 20 mg/g cream • once daily application, 3 weeks Drug: E LEO 35299 10 mg/g solution • once daily application, 3 weeks Drug: F LEO 35299 10 mg/g solution • once daily application, 3 weeks Drug: Daivonex® ointment • once daily application, 3 weeks Drug: Daivonex® ointment vehicle • once daily application, 3 weeks

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change in the 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 Clinical Score. Total Clinical Score	Baseline to Day 22

	range from 0 (all symptoms absent) to 9 (all symptoms severe)	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change in Erythema From Baseline to 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 in Infiltration From Baseline to 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 in Scaling From Baseline to 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 From Baseline to Day 22	Change in total skin thickness measured by ultrasound from baseline to end of treatment	Baseline to Day 22
Change in Skin Thickness From Baseline to Day 22	Change in skin thickness - echo-poor band measured by ultrasound from baseline to end of treatment	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 l'Archet 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

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Study Registration Dates

First Submitted
2012-04-16

First Submitted that Met QC Criteria
2012-04-18

First Posted (Estimated)

2012-04-19

Results Reporting Dates

Results First Submitted
2013-08-19

Results First Submitted that Met QC Criteria
2013-11-08

Results First Posted (Estimated)
2013-12-30

Study Record Updates

Last Update Submitted that met QC Criteria
2013-11-08

Last Update Posted (Estimated)
2013-12-30

Last Verified
2013-11

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Dermatologic Agents
Calcium Regulating Hormones and Agents
Physiological Effects of Drugs
Calcium Channel Agonists
Membrane Transport Modulators
Molecular Mechanisms of Pharmacological Action
Vasoconstrictor Agents
Vitamins

Micronutrients
Bone Density Conservation Agents
Calcitriol
Calcipotriene
Pharmaceutical Solutions

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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COMPLETED

Blinded Study of Topical Investigational Lotion Vs. Approved Cream in Treatment of Plaque Psoriasis

ClinicalTrials.gov ID **NCT01166646**

Sponsor Therapeutics, Inc.

Information provided by Therapeutics, Inc. (Responsible Party)

Last Update Posted 2016 05 16

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to determine whether the investigational lotion is an effective treatment of moderate to severe plaque psoriasis in comparison to an approved cream.

Feedback

Conditions

Plaque Psoriasis

Intervention / Treatment

- Drug: Halobetasol Proprionate Lotion 0.05%
- Drug: Halobetasol Proprionate Cream 0.05%

Other Study ID Numbers

- 000 0551 202

Study Start

2010 07

Primary Completion (Actual)

2011 07

Study Completion (Actual)

2011 07

Enrollment (Actual)

43

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: Halobetasol propionate (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Halobetasol+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

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

Michigan Locations

Clinton Township, Michigan, United States, 48038
Michigan Center for Skin Care Research (dba Skin Care 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:

- Subjects are male or non pregnant female; 18 years of age at the time of screening.
- Subjects provide Institutional Review Board (IRB) approved written informed consent for participating in this study.
- Subjects have a clinical diagnosis of stable plaque psoriasis involving a minimum of 20% body surface area and an Overall Disease Severity (ODS) score on the designated treatment area of at least 3 as determined by the evaluating investigator.
- Subjects are willing and able to apply the study medication as directed, comply with study instructions and commit to all follow up visits for the duration of the study.
- Women of childbearing potential (WOCBP) must have a negative urine pregnancy test at the Screening (Part B) and Baseline Visits and agree to use an effective form of birth control for the duration of the study (abstinence, stabilized on oral contraceptives or contraceptive patches for at least three months, implant, injection, IUD, NuvaRing®, condom and spermicidal or diaphragm and spermicidal). Abstinence is an acceptable form of birth control for subjects who are not sexually active. Subjects who become sexually active during the trial must agree to use an effective, non prohibited form of birth control for the duration of the study.

Exclusion Criteria:

- Subjects have spontaneously improving or rapidly deteriorating plaque psoriasis, or have guttate, pustular, erythrodermic or other non plaque forms of psoriasis.
- Subjects have a physical condition which, in the Investigator s opinion, might impair evaluation of plaque psoriasis, adrenal axis function (e.g., Addison s Disease, Cushing s Syndrome) or which exposes the subject to an unacceptable risk by study participation.
- Subjects have used any phototherapy (including laser), photo chemotherapy or systemic psoriasis therapy including methotrexate, retinoids, cyclosporine or biologics within 30 days prior to the initiation of study medication treatment.
- Subjects have used systemic corticosteroids (including oral or intramuscular) or topical, inhaled or intranasal corticosteroids within 30 or 14 days, respectively, prior to Part B of the Screening Visit and/or subjects have used systemic or topical corticosteroids between the Screening Visit and the initiation of treatment.
- Subjects have had prolonged exposure to natural or artificial sources of ultraviolet radiation within 30 days prior to the initiation of treatment or are intending to have such exposure during the study that is thought by the Investigator to likely modify the subject s disease.
- Subjects have used topical psoriatic therapy including tar, anthralin, retinoids, vitamin D analogs (e.g., Dovonex®) within 14 days prior to the initiation of study medication treatment.
- Subjects have used emollients/moisturizers on areas to be treated within one day prior to the initiation of study medication treatment.
- Subjects are currently using lithium or plaquenil.

- Subjects are currently using a beta blocking medication (e.g., propanolol) or angiotensin converting enzyme (ACE) inhibitors at a dose that has not been stabilized, in the opinion of the Investigator.
- Subjects have a history of sensitivity to any of the ingredients in the study medication.
- Subjects are pregnant, nursing or planning a pregnancy during the study period.
- Subjects are currently enrolled in an investigational drug or device study.
- Subjects have received an investigational drug or an investigational device within 30 days prior to screening.
- Subjects have been previously enrolled in this study and treated with the study medication.
- Subjects have irregular sleep schedules or work night shifts (cortisol levels exhibit physiological diurnal variation).
- Subjects have a screening CST with a post 30 minute stimulation cortisol level of ≤ 18 µg/dL.

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 (Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Halobetasol Proprionate Lotion 0.05% Subjects randomized to receive lotion	Drug: Halobetasol Proprionate Lotion 0.05% • Apply 3.5 grams twice daily for 1-2 weeks
Active Comparator: Halobetasol Proprionate Cream 0.05% Subjects randomized to receive cream	Drug: Halobetasol Proprionate Cream 0.05% • Apply 3.5 grams twice daily for 1-2 weeks • Other Names: ◦ Ultravate

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Adrenal Suppression Potential	Hypothalamic Pituitary-Adrenal (HPA)-Axis responses to Cosyntropin Stimulation Testing (CST) were dichotomized to normal and abnormal. An abnormal HPA Axis response (HPA Suppression) was defined as a 30-minute post-stimulation serum cortisol level of ≤18 µg/dL at the end of treatment.	After 1-2 weeks dose
Pharmacokinetic Properties (Cmax)	Comparison of PK results (peak concentration in plasma [Cmax]) between the two Treatment	Day 8

	Groups will be conducted following the last application of the medication on Day 8.	
Pharmacokinetic Properties (Tmax)	Comparison of PK results (time to peak concentration [Tmax]) between the two Treatment Groups will be conducted following the last application of the medication on Day 8.	Day 8
Pharmacokinetic Properties (AUC)	Comparison of PK results (area under the curve [AUC] from time 0 to infinity) between the two Treatment Groups will be conducted following the last application of the medication on Day 8.	Day 8

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Changes in Disease Severity (Success)	Overall disease severity (ODS) will be recorded at baseline, Day 8, and Day 15 on a 0 (clear) to 4 (severe/very severe) point scale. ODS evaluations will be dichotomized to "success" and "failure" with success defined as a grade of 1 or 0 at the end of treatment (EOT).	Day 15
Number of Subjects Whose Signs of Psoriasis Was Designated "Success"	Signs of psoriasis including scaling, erythema, and plaque elevation will be recorded at baseline, Day 8, and Day 15 on a 0 (clear) to 4 (severe/very severe) point scale. Each of the signs of psoriasis will be dichotomized to a) "success" and "failure" with success defined as a grade of 1 or 0 at the End of Treatment (EOT; i.e., the visit at which psoriasis has cleared [Day 8 or Day 15] or end of the assigned treatment period).	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

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
2010-07-19

First Submitted that Met QC Criteria
2010-07-19

First Posted (Estimated)
2010-07-21

Results Reporting Dates

Results First Submitted
2016-03-10

Results First Submitted that Met QC Criteria
2016-04-11

Results First Posted (Estimated)
2016-05-16

Study Record Updates

Last Update Submitted that met QC Criteria
2016-04-11

Last Update Posted (Estimated)
2016-05-16

Last Verified
2016-04

More Information

Terms related to this study

Additional Relevant MeSH Terms

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

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).

COMPLETED

Moderate to Severe Plaque Psoriasis With Scalp Involvement

ClinicalTrials.gov ID NCT00791765

Sponsor Amgen

Information provided by Amgen (Responsible Party)

Last Update Posted 2014 07 23

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to determine if etanercept is effective in the treatment of scalp involvement in moderate to severe plaque psoriasis.

Official Title

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

Conditions

Psoriasis

Intervention / Treatment

- Biological: Etanercept
- Biological: Placebo

Other Study ID Numbers

- 20080014

Study Start

2008 10

Primary Completion (Actual)

2010 01

Study Completion (Actual)

2010 03

Enrollment (Actual)

124

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)

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:

- Must provide written informed consent before any study specific procedure
- Be male or female greater than or equal to 18 years of age at time of screening
- Has stable moderate to severe plaque psoriasis for at least 6 months
- Affected body surface area (BSA) greater than or equal to 10%
- Psoriasis Area and Severity Index (PASI) score greater than or equal to 10
- At least 30 percent affected scalp surface area
- Psoriasis Scalp Severity Index (PSSI) score greater than or equal to 15
- Candidate for systemic therapy or phototherapy in the opinion of the investigator
- Negative test for hepatitis B surface antigen, hepatitis C antibody, and Human Immunodeficiency Virus (HIV)
- Negative serum pregnancy test for female subjects (unless 3 years post menopausal or surgically sterile)
- Willing to use medically acceptable form of birth control for duration of study
- Negative Purified Protein Derivative (PPD) within 30 days prior to first dose of study drug

Exclusion Criteria:

- Any active infection
- Significant concurrent medical conditions, including: Insulin dependent diabetes mellitus; Congestive heart failure; Myocardial infarction within last year; Unstable angina pectoris; Uncontrolled hypertension; Severe pulmonary disease [requiring oxygen therapy or hospitalization]; Systemic lupus erythematosus; Multiple sclerosis or any other demyelinating disease; Active malignancy
- Any condition, in opinion of study doctor, that might cause this study to be detrimental to subject
- History of cancer within 5 years before first dose of study drug
- Skin conditions other than psoriasis that would interfere with evaluations of the effect of study medications on psoriasis
- Presence of guttate, erythrodermic or pustular psoriasis
- Use of topical cyclosporine or calcineurin inhibitors within 14 days of first dose of study drug
- Use of tar shampoos within 14 days of first dose of study drug
- Use of following therapies within 28 days of first dose of study drug: IV or oral cyclosporine or calcineurin inhibitors, Ultraviolet Light A therapy, Psoralen plus ultraviolet A radiation, Oral retinoids, Ultraviolet Light B therapy, Topical steroids or steroid shampoo, Topical vitamin A or D analog preparations, Anthralin, other systemic psoriasis therapy, cyclophosphamide, sulfasalazine, anakinra
- Use of Alefacept (Amevive), Efalizumab (Raptiva), Anti tumor necrosis factor (TNF) biologic therapies within 3 months of the first dose of study drug. Prior anti TNF use will not be permitted if discontinued due to lack of efficacy, an adverse event, or non compliance.
- Use of interleukin (IL) 12/IL 23 within 6 months of the first dose of study drug

- Participation in another clinical trial within 90 days or 5 half lives (whichever is longer) of randomization
- Laboratory abnormalities at screening: hemoglobin less than 11 g/dL, platelet count less than 125,000/mm^3, white blood cell count less than 3,500 cells/mm^3, aspartate aminotransferase (AST)/alanine aminotransferase (ALT) greater than or equal to 1.5 x the upper limit of normal, any other laboratory abnormality which will prevent patient from completing the study or interfere with interpretation of study results
- Patient is pregnant or breast feeding
- Presence of any condition that could compromise the patient s ability to participate in the study, such as a history of substance abuse or psychiatric 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: Placebo BIW/Etanercept 50 mg BIW Participants received placebo subcutaneous injections twice per week (BIW) for the first 12 weeks of the study. From Week 12 to Week 24, participants received etanercept 50 mg BIW.	Biological: Etanercept • Etanercept for subcutaneous injection. • Other Names: ◦ Enbrel® Biological: Placebo • Placebo for subcutaneous injection.
Experimental: Etanercept 50 mg BIW/Etanercept 50 mg QW Participants received etanercept 50 mg by subcutaneous injection twice per week (BIW) for the first 12 weeks of the study. From Week 12 to Week 24, participants received etanercept 50 mg once per week (QW) and placebo once per week.	Biological: Etanercept • Etanercept for subcutaneous injection. • Other Names: ◦ Enbrel® Biological: Placebo • Placebo for subcutaneous injection.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage Change From Baseline in Psoriasis Scalp Severity Index at Week 12	The Psoriasis Scalp Severity Index (PSSI) measures the extent of psoriasis involvement and the severity of erythema, infiltration, and desquamation of the scalp. Involvement and severity of psoriasis for the PSSI is scored by physicians using a scale from 0 to 72, where 0 = no psoriasis, and higher scores indicating more severe disease. The PSSI calculation does not include the face or neck area.	Baseline and Week 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With PSSI 75% Response at Week 12	Percentage of participants achieving at least a 75% improvement from baseline in the Psoriasis Scalp Severity Index (PSSI) at Week 12. The Psoriasis Scalp Severity Index (PSSI) measures the extent of psoriasis involvement and the severity of erythema, infiltration, and desquamation of the scalp. Involvement and severity of psoriasis for the PSSI is scored by physicians using a scale from 0 to 72, where 0 = no psoriasis, and higher scores indicating more severe disease. The PSSI calculation does not include the face or neck area. PSSI 75 indicates at least a 75% improvement in the PSSI score from baseline.	Baseline and Week 12
Percent Change From Baseline in PSSI at Week 24 in Participants Switching From	Percent change from baseline in Psoriasis Scalp Severity Index (PSSI) in participants switching from placebo to etanercept at Week 12 (Group B) at Week 24. The PSSI measures the extent of psoriasis involvement and the severity of erythema, infiltration, and desquamation of the	Baseline and Week 24

Placebo to Etanercept at Week 12	scalp. Involvement and severity of psoriasis for the PSSI is scored by physicians using a scale from 0 to 72, where 0 = no psoriasis, and higher scores indicate more severe disease. The PSSI calculation does not include the face or neck area.	
Patient Satisfaction With Treatment at Week 12	This response scale was adapted from the Medical Outcomes Study: Patient Satisfaction Survey. To assess satisfaction with treatment, the participant was asked to check a box (from "very dissatisfied" to "very satisfied") to indicate his or her level of satisfaction with the medications control of psoriasis.	12 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, Lynde C, Tyring S, Kricorian G, Shi Y, Klekotka P. Moderate to severe plaque psoriasis with scalp involvement: a randomized, double blind, placebo (https://pubmed.ncbi.nl

controlled study of etanercept. J Am Acad Dermatol. 2012 Jul;67(1):86 92. doi: 10.1016/j.jaad.2011.07.034. Epub 2011 Oct 20. m.nih.gov/22014541)

- Tyring S, Bagel J, Lynde C, Klekotka P, Thompson EH, Gandra SR, Shi Y, Kricorian G. Patient reported outcomes in moderate to severe plaque psoriasis with scalp involvement: results from a randomized, double blind, placebo controlled study of etanercept. J Eur Acad Dermatol Venereol. 2013 Jan;27(1):125 8. doi: 10.1111/j.1468 3083.2011.04394.x. Epub 2011 Dec 21. No abstract available. (https://pubmed.ncbi.nlm.nih.gov/22188302)

*** 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
2008-11-14

First Submitted that Met QC Criteria
2008-11-14

First Posted (Estimated)
2008-11-17

Results Reporting Dates

Results First Submitted
2010-09-03

Results First Submitted that Met QC Criteria
2013-09-04

Results First Posted (Estimated)
2013-11-07

Study Record Updates

Last Update Submitted that met QC Criteria

2014-07-14

Last Update Posted (Estimated)

2014-07-23

Last Verified

2014-07

More Information

Terms related to this study

Keywords Provided by Amgen

Scalp
Psoriasis
Plaque Psoriasis
Skin Diseases
Moderate to severe plaque psoriasis
etanercept

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

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COMPLETED

First Study of Secukinumab in Pre-filled Syringes in Subjects With Chronic Plaque-type Psoriasis: Response at 12 Weeks (FEATURE)

ClinicalTrials.gov ID NCT01555125

Sponsor Novartis Pharmaceuticals

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

Last Update Posted 2018 08 08

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to demonstrate efficacy of secukinumab at Week 12 based on PASI and IGA response rates versus placebo in subjects with moderate to severe chronic plaque type psoriasis.

Feedback

Official Title

A Randomized, Double blind, Placebo Controlled, Multicenter Study of Subcutaneous Secukinumab in Prefilled Syringes to Demonstrate Efficacy After Twelve Weeks of Treatment, and to Assess the Safety, Tolerability, Usability and Long term Efficacy in Subjects With Chronic Plaque type Psoriasis

Conditions

Moderate to Severe Plaque type Psoriasis

Intervention / Treatment

- Drug: secukinumab 150 mg
- Drug: secukinumab 300 mg
- Drug: placebo

Other Study ID Numbers

- CAIN457A2308
- 2011 006057 28 (EudraCT Number)

Study Start (Actual)

2012 05 08

Primary Completion (Actual)

2016 10 24

Study Completion (Actual)

2016 10 24

Enrollment (Actual)

177

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

Alabama Locations

Birmingham, Alabama, United States, 35205
Novartis Investigative Site

Mobile, Alabama, United States, 36608
Novartis Investigative Site

Arizona Locations

Glendale, Arizona, United States, 85308



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 and severe plaque type psoriasis diagnosed for at least 6 months.
- Severity of psoriasis disease meeting all of the following three criteria:

Psoriasis Area and Severity Index (PASI) score of 12 or greater, Investigator s Global Assessment (IGA) score of 3 or greater, Total body surface area (BSA) affected of 10% or greater.

Inadequate control by prior use of topical treatment, phototherapy and/or systemic therapy.

Exclusion criteria:

- Current forms of psoriasis other than chronic plaque type psoriasis (for example, pustular, erythrodermic, guttate).
- Current drug induced psoriasis.
- Previous use of secukinumab or any drug that targets IL 17 or IL 17 receptor.
- Significant medical problems such as uncontrolled hypertension, congestive heart failure or a condition that significantly immunocompromises the subject.
- Hematological abnormalities.
- History of an ongoing, chronic or recurrent infectious disease, or evidence of untreated tuberculosis.
- History of lymphoproliferative disease or history of malignancy of any organ system within the past 5 years.
- 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 : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: secukinumab 150 mg Drug	Drug: secukinumab 150 mg • After the data base lock of week 52 data has been performed, subjects will receive secukinumab 150 mg treatment as open label for the remainder of the extension treatment period
Experimental: secukinumab 300 mg Drug	Drug: secukinumab 300 mg • After the data base lock of week 52 data has been performed, subjects will receive secukinumab 300 mg treatment as open label for the remainder of the extension treatment period
Placebo Comparator: placebo	Drug: placebo • Subjects who were on placebo at Week 52 cannot continue in the extension treatment period

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Efficacy of Secukinumab Compared to Placebo in Subjects With Moderate to Severe Chronic Plaque-type Psoriasis at Week 12 Measure: PASI 75 (Psoriasis Area and Severity Index) Response.	A 75% reduction in the Psoriasis Area and Severity Index (PASI) score (PASI 75) is the current benchmark of primary endpoints for most clinical trials of psoriasis	12 weeks
Efficacy of Secukinumab Compared to Placebo in Subjects With Moderate to Severe Chronic Plaque-type Psoriasis Measure:IGA (Investigator s Global Assessment) With a 0 or 1 Response at Week 12	The IGA 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 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 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	12 weeks

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Absolute Change From Baseline in Self Injection Assessment Questionnaire (SIAQ) Domain Scores at Week 12	The three domains of the POST SIAQ are feelings about injections, self-image, self-confidence, injection-site reactions, ease of use, and satisfaction with self-injection. The SIAQ items are scored on a semantic Likert-type scale where lower numbers indicate a worse experience. Domain scores range from 0 to 10. Subjects self-injecting at this visit completed this SIAQ questionnaire. The POST-SIAQ is taken after the injection at that visit.	Week 12
Absolute Change From Baseline in Self-Injection Assessment Questionnaire (SIAQ) Domain Scores at Week 48	The three domains of the POST SIAQ are feelings about injections, self-image, self-confidence, injection-site reactions, ease of use, and satisfaction with self-injection. The SIAQ items are scored on a semantic Likert-type scale where lower numbers indicate a worse experience. Domain scores range from 0 to 10. Subjects self-injecting at this visit completed this SIAQ questionnaire. The POST-SIAQ is taken after the injection at that visit.	Baseline, week 48
Number of Subjects With Potential Use Related Hazards at Week 1	To assess potential use-related hazards with the secukinumab PFS for the subject	Week 1
Percentage of Subjects With Successful Self Administration of Study Drug at Week 1	To assess the subject s ability to follow instructions for use with the secukinumab PFS	Week 1

Percent of Responders With Psoriasis Area and Severity Index (PASI) Equal to or Greater Than 50, PASI 75, PASI 90, PASI 100, (Induction) With Non-responder Imputation	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 50, 75, 90 and 100 were defined as participants achieving ≥ 50%, 75%, 90% or 100% improvement from baseline.	Week 12
Percent of Responders With Psoriasis Area and Severity Index (PASI) Equal to or Greater Than 50, PASI 75, PASI 90, PASI 100, (Maintenance; Observed Data)	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 50, 75, 90 and 100 were defined as participants achieving ≥ 50%, 75%, 90% or 100% improvement from baseline.	Week 52
Percent of Responders With Investigator s Global Assessment	The IGA mod 2011 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 =	Week 52

(IGA) Mod 2011 Score of 0 or 1, (Maintenance; Observed Data)	clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe.	
Absolute Change From Baseline for PASI Score at Week 12, (Induction)	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:01, arms:0.2 body:0.3 legs:0.4)	Week 12
Absolute Change From Baseline for PASI Score Over Time up to Week 52, (Maintenance; Observed Data)	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:01, arms:0.2 body:0.3 legs:0.4)	Week 52

Number of Participants in Each Investigator s Global Assessment (IGA) Mod 2011 Category at Week 12, (Induction)	The IGA mod 2011 category 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 and 4 = severe	Week 12
Percentage of Participants in Each Investigator s Global Assessment (IGA) Mod 2011 Category Over Time up to Week 52, (Maintenance; Observed Data)	The IGA mod 2011 category 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 and 4 = severe.	Week 52
Change From Baseline in EQ-5D at Week 12 (Induction)	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)	Week 12
Change From Baseline in EuroQOL 5-	ED-5Q: Participant rated questionnaire to assess health related quality of life in terms of a single utility score. Five domains are assessed mobility,	Week 52

Dimension Health Status Questionnaire (EQ-5D) Over Time up to Week 52, (Maintenance)	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)	
Median Percentage Change From Baseline in Dermatology Life Quality Index (DLQI) Total Score, (Induction)	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. This result was reflected in the percentage change from baseline at Week 12, higher reductions (improvements) in DLQI scores (median treatment difference).	Baseline and week 12
Median Percentage Change From Baseline in Dermatology Life Quality Index (DLQI) Score Over Time up to Week 52, (Maintenance)	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. This result was reflected in the percentage change from baseline at Week 12, higher reductions (improvements) in DLQI scores (median treatment difference).	Baseline and week 52

Percentage of Participants Achieving a DLQI Score of 0 or 1 at Week 12, (Induction)	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	Week 12
Percentage of Participants Achieving a DLQI Score of 0 or 1 Over Time up to Week 52, (Maintenance)	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	Week 52
Number of Responders With PASI Equal to or Greater Than 50, PASI 75, PASI 90, PASI 100 After Week 52	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 50, 75, 90 and 100 were defined as participants achieving ≥	Week 172

	50%, 75%, 90% or 100% improvement from baseline.	
Absolute Change From Baseline for PASI Score After Week 52, (Observed Data)	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:01, arms:0.2 body:0.3 legs:0.4)	Week 172
Number of Participants in Each IGA Mod 2011 Category After Week 52 (Observed Data)	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 172
Number of Participants Developing Treatment Emergent Anti-secukinumab Antibodies, Immunogenicity	The development of anti-secunimubab anti-bodies will decrease a participant s ability to respond to secukinumab treatment. The number of participants developing anti-secukinumab anti-bodies was measured from Baseline to 8 weeks after last treatment	Baseline and at Week 12, 24, 52, 100, 148, and 196, 204

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
2012-03-13

First Submitted that Met QC Criteria
2012-03-14

First Posted (Estimated)
2012-03-15

Results Reporting Dates

Results First Submitted
2017-10-20

Results First Submitted that Met QC Criteria
2018-08-07

Results First Posted
2018-08-08

Study Record Updates

Last Update Submitted that met QC Criteria
2018-08-07

Last Update Posted
2018-08-08

Last Verified
2018-08

More Information

Terms related to this study

Keywords Provided by Novartis (Novartis Pharmaceuticals)

Psoriasis

Additional Relevant MeSH Terms

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

Study Documents

No study documents available

Record 1 of 1

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COMPLETED

NB-UVB Phototherapy With and Without Topical LCD Treatment: a Bilateral Pilot Study

ClinicalTrials.gov ID **NCT00708851**

Sponsor NeoStrata Company, Inc.

Information provided by NeoStrata Company, Inc. (Responsible Party)

Last Update Posted 2015 04 20

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to determine if combining a daily at home regimen using an LCD Solution with a 3 times weekly outpatient narrowband UVB phototherapy regimen could be a safe, effective, rapid, and, convenient treatment for plaque psoriasis.

Feedback

Detailed Description

Use of coal tar with narrowband (NB) ultraviolet B (UVB) light (the Goeckermen regimen) is an effective treatment for plaque psoriasis that has become impractical in outpatient care mainly due to the inconvenience and aesthetic concerns of coal tar. This study aims to evaluate the safety, efficacy, and convenience of adding a novel liquor carbonis distillate (LCD) (coal tar) solution to standard NB_UVB phototherapy in adults with chronic plaque psoriasis. Patients will apply LCD solution to half the body, twice daily at home and receive outpatient full body NB UVB light therapy 3 times a week for up to 12 weeks. A blinded investigator will grade psoriasis severity of body halves and bilateral target lesions and monitor adverse reactions. Patients will rate their psoriasis symptoms and LCD solution aesthetics. Incorporating an at home regimen with a novel LCD solution into outpatient NB UVB light therapy is safe, convenient, and effective and can improve psoriasis more quickly than NB UVB light therapy alone.

Official Title

A Clinical Evaluation of Safety & Efficacy of Adding an At home Topical LCD Solution Regimen to Standard Narrowband UVB Phototherapy Administered 3 Times Weekly to Adults With Generalized Plaque Psoriasis.

Conditions

Plaque Psoriasis

Intervention / Treatment

- Other: LCD Solution with NB UVB Phototherapy
- Device: NB UVB Light Device (311 315 nm)

Other Study ID Numbers

- 07 LCDUVB

Study Start

2007 04

Primary Completion (Actual)

2008 01

Study Completion (Actual)

2008 03

Enrollment (Actual)

12

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)

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

New Jersey Locations

East Windsor, New Jersey, United States, 08520

Windsor Dermatology

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:

- 18 years old or older
- able and willing to provide written informed consent
- symmetrical plaque psoriasis
- able and willing to attend phototherapy sessions and apply LCD at home
- negative pregnancy test for women of child bearing potential

Exclusion Criteria:

- current or recent other treatments for psoriasis
- hypersensitivity to LCD or UVB light
- current or previous skin cancer
- pregnant or nursing mother
- participating in another clinical 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

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Single Group Assignment
Masking : Single (Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Active Comparator: NB-UVB Light Device (311-315 nm) the subject will receive full body NB-UVB light therapy	Device: NB-UVB Light Device (311-315 nm) • NB-UVB Phototherapy: 3 light exposures / week • Other Names: ◦ Ultralite Model # V4848NB
Experimental: LCD Solution with NB-UVB Phototherapy on half of the body will receive LCD while the full body receives NB-UVB therapy	Other: LCD Solution with NB-UVB Phototherapy • LCD Solution: 2 applications / day NB-UVB Phototherapy: 3 light sessions / week • Other Names: ◦ LCD Device: NB-UVB Light Device (311-315 nm) • NB-UVB Phototherapy: 3 light exposures / week • Other Names: ◦ Ultralite Model # V4848NB

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Difference in Bilateral Static Physicians Global	Twelve (12) participants were followed over a 12-week treatment period. Treatment was administered bilaterally as they applied LCD solution to one half of their body while receiving full-body NB-UVB light therapy. The difference in	12 weeks of treatment

Assessment (sPGA) Scores, and Erythema, Scaling, and Induration (ESI) Scores of Bilateral Target Lesion Scores Across Visits for Each Condition and Between Conditions.	their sPGA, and ESI scores of bilateral target lesions were measured across all visits. PGA scores are calculated using a 6-point scale from 0 (clear) to 5 (very severe). Erythema, induration and scaling scores use a 5-point scale from 0 (none) to 4 (very severe).	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Difference in Number and Severity of Treatment-related Adverse Reactions Between Conditions.	Number of subjects who experienced and adverse reaction due to UVB + LCD, versus number of subjects who experienced an adverse reaction due to UVB therapy alone.	12 weeks of treatment

Collaborators and Investigators

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

Sponsor

NeoStrata Company, Inc.

Collaborators

No information provided

Investigators

- Principal Investigator: Jerry Bagel, MD, Windsor Dermatology, East Windsor, NJ 08520

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
2008-06-27

First Submitted that Met QC Criteria
2008-07-01

First Posted (Estimated)
2008-07-02

Results Reporting Dates

Results First Submitted
2014-11-13

Results First Submitted that Met QC Criteria
2015-04-02

Results First Posted (Estimated)

2015-04-20

Study Record Updates

Last Update Submitted that met QC Criteria

2015-04-02

Last Update Posted (Estimated)

2015-04-20

Last Verified

2015-04

More Information

Terms related to this study

Keywords Provided by NeoStrata Company, Inc.

psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

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Record 1 of 1

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COMPLETED

Evaluation of Cardiovascular Risk Markers in Psoriasis Patients Treated With Secukinumab (CARIMA)

ClinicalTrials.gov ID **NCT02559622**

Sponsor Novartis Pharmaceuticals

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

Last Update Posted 2017 07 13

Study Details Tab

Study Overview

Brief Summary

The purpose of this study was to explore the effect of treatment with 300 mg or with 150 mg secukinumab (administered weekly for 4 weeks followed by four weekly administration) on endothelial dysfunction and arterial stiffness after 12 weeks and for up to 52 weeks in subjects with

Feedback

chronic plaque type psoriasis. Furthermore soluble biomarkers were assessed to evaluate the influence of secukinumab on cardiovascular risk. Magnetic resonance imaging (MRI) was performed in a sub population to assess the treatment effect on arterial vessel wall morphometry in atherosclerosis prone vascular beds.

Official Title

A Randomized, Double blind, Placebo controlled, Multicenter, Exploratory Evaluation of Surrogate Markers of Cardiovascular Risk in Patients With Active Chronic Plaque type Psoriasis Treated for up to 52 Weeks With Subcutaneous (s.c.) Secukinumab (300 mg or 150 mg).

Conditions

Psoriasis

Intervention / Treatment

- Drug: Secukinumab
- Other: Placebo
- Other: Placebo
- Drug: Secukinumab

Other Study ID Numbers

- CAIN457ADE02

Study Start

2014 04

Primary Completion (Actual)

2016 04

Study Completion (Actual)

2016 04

Enrollment (Actual)

151

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.

Germany

- **Augsburg, Germany, 86179**
  Novartis Investigative Site
- **Berlin, Germany, 10789**
  Novartis Investigative Site
- **Berlin, Germany, 13187**
  Novartis Investigative Site
- **Bielefeld, Germany, 33647**
  Novartis Investigative Site
- **Bochum, Germany, 44791**
  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

Key Inclusion Criteria:

- Chronic moderate to severe plaque type psoriasis for at least 6 months prior to randomization with a Psoriasis Area and Severity Index (PASI) score ≥ 10 at randomization.
- Inadequate response, intolerance or contraindication to cyclosporine, methotrexate and psoralen plus ultraviolet A light treatment (PUVA) as documented in the patient s medical history or reported by the patient or determined by the investigator at screening. Relative contraindications such as interference of patient s lifestyle with the treatment are accepted.

Key Exclusion Criteria:

- Forms of psoriasis other than chronic plaque type (e.g., pustular, erythrodermic and guttata psoriasis) at screening or randomization.
- Ongoing use of prohibited psoriasis and non psoriasis treatments.

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: 300 mg secukinumab 300 mg secukinumab every week for 4 weeks followed by 300 mg secukinumab every 4 weeks until week 48 (last injection)	Drug: Secukinumab • 300 mg secukinumab • Other Names: ◦ AIN457
Experimental: 150 mg secukinumab 150 mg secukinumab every week for 4 weeks followed by 150 mg secukinumab every 4 weeks until week 48 (last injection)	Drug: Secukinumab • 150 mg secukinumab • Other Names: ◦ AIN457
Other: Placebo followed by 300 mg secukinumab Placebo until week 12 followed by 300 mg secukinumab every week for 4 weeks followed by 300 mg secukinumab every 4 weeks until week 48 (last injection)	Other: Placebo • Placebo followed by 300 mg secukinumab

Other: Placebo followed by 150 mg secukinumab Placebo until week 12 followed by 150 mg secukinumab every week for 4 weeks followed by 150 mg secukinumab every 4 weeks until week 48 (last injection)	Other: Placebo • Placebo followed by 150 mg secukinumab

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Flow Mediated Dilation (FMD) at Week 12 Followed by Secukinumab 300 mg vs Pooled Placebo Treatment	Flow Mediated Dilation (FMD) is non-invasive method evaluated by Doppler Ultrasound test, to assess endothelial function. FMD was calculated as the percent maximal deviation from the baseline arterial diameter (D):FMD = 100*[(D maximum - D baseline) / D baseline]. Here, arterial diameter (brachial artery) was measured at rest (1 minute), during inflation of the distal cuff to 100 millimeter of mercury (mmHg) for 4.5 minutes and for 4.5 minutes following deflation.	Week 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Change From Baseline in Flow Mediated Dilation (FMD) at Week 4, 12, 24 and 52	FMD is non-invasive method evaluated by Doppler Ultrasound test, to assess endothelial function. FMD was calculated as the percent maximal deviation from the baseline arterial diameter (D):FMD = 100*[(D maximum - D baseline) / D baseline]. Here, arterial diameter (brachial artery) was measured at rest (1 minute), during inflation of the distal cuff to 100 mmHg for 4.5 minutes and for 4.5 minutes following deflation. A positive change in FMD constitutes an improvement in endothelial function.	Baseline, Week 4, 12, 24 and 52
Change From Baseline in Aortic Augmentation Index at Heart Rate of 75 (AIx-75) at Week 4, 12, 24 and 52	Pulse wave analysis was performed on the central aortic pressure waveform as derived by SphygmoCor XCEL from the brachial pressure waveform recorded in a partially-inflated blood pressure cuff around the upper arm. The waveform derivation employs a validated generalized transfer function to convert a brachial waveform to a central waveform and has been shown to produce measurement results corresponding to measurements using intra-arterial pressure catheters. The augmentation index is derived from the waveform by determining the percentage of the central pulse pressure during systole due to wave reflection. AIx was heart-rate corrected to calculate the AIx at a heart rate of 75 bpm, i.e. AIx-75.	Baseline, Week 4, 12, 24 and 52
Change From Baseline in Pulse Wave Velocity (PWV) at Week 4, 12, 24 and 52	Regional arterial pulse wave velocity (PWV) was directly related to arterial stiffness and was defined as the time it takes for the blood pressure wave to travel from a proximal site to a distal site (relative to the heart) divided by the distance (PWV = Δdistance/Δtime [m/s]). The foot of the arterial pulse wave was being recorded by using the SphygmoCor XCEL device. XCEL simultaneously measures the pressure	Baseline, Week 4, 12, 24 and 52

	waveform at the femoral site (using a partially inflated custom blood pressure cuff) and the carotid site (using hand-held applanation tonometry). The foot-to-foot time between the two pressure waveforms was the time interval used in the PWV calculation.	
Change From Baseline in Average Wall Area Assessed as a Measure of Total Plaque Burden at Week 12	Magnetic resonance imaging (MRI) was used to evaluate vessel wall morphometry to determine plaque burden. As a measure of plaque burden, average wall area was computed by subtracting vessel lumen area from total vessel area. Exploratory 3.0 Tesla MRI technique was applied to assess structure and function of the carotid and the aorta. A 2D axial dark blood T1, T2, proton density weighted spin echo based images and time of flight images were acquired from the bilateral carotid arteries as well as the descending aorta.	Baseline, Week 12
Change From Baseline in Average Wall Area Assessed as a Measure of Total Plaque Burden at Week 52	Magnetic resonance imaging (MRI) was used to evaluate vessel wall morphometry to determine plaque burden. As a measure of plaque burden, average wall area was computed by subtracting vessel lumen area from total vessel area. Exploratory 3.0 Tesla MRI technique was applied to assess structure and function of the carotid and the aorta. A 2D axial dark blood T1, T2, proton density weighted spin echo based images and time of flight images were acquired from the bilateral carotid arteries as well as the descending aorta.	Baseline, Week 52
Change From Baseline in High Sensitivity C-reactive Protein (hsCRP) at Week 4, 12, 24 and 52	High sensitivity C-reactive protein (hsCRP), a soluble biomarker of systemic inflammation was determined in fasting blood samples to evaluate the effect of secukinumab on systemic inflammation.	Baseline, Week 4, 12, 24 and 52

Change From Baseline in S-100 Protein B (Total) at Week 4, 12, 24 and 52	S100 calcium-binding protein B (S100B-protein), a soluble biomarker of systemic inflammation was determined in fasting blood samples to evaluate the effect of secukinumab on systemic inflammation.	Baseline, Week 4, 12, 24 and 52
Change From Baseline in Chemokine (C-c Motif) Ligand 5 (CCL5), Monocyte Chemoattractant Protein 1 (MCP-1) and Macrophage Inflammatory Proteins (MIP) 1 Alpha and 1 Beta at Week 4, 12, 24 and 52	Chemokine (c-c motif) ligand 5 (CCL5), Monocyte chemoattractant protein 1 (MCP-1) and Macrophage inflammatory proteins (MIP) 1 alpha (1A) and 1 beta (1B), soluble biomarkers of systemic inflammation were determined in fasting blood samples to evaluate the effect of secukinumab on systemic inflammation.	Baseline, Week 4, 12, 24 and 52
Change From Baseline in Fasting Plasma Glucose (FPG) at Week 4, 12, 24 and 52	Fasting plasma glucose (FPG), a soluble biomarker of Dysglycemia was determined in fasting blood samples to evaluate the effect of secukinumab on systemic inflammation.	Baseline, Week 4, 12, 24 and 52
Change From Baseline in Fasting Insulin at Week 4, 12, 24 and 52	Fasting Insulin, a soluble biomarker of Dysglycemia was determined in fasting blood samples to evaluate the effect of secukinumab on Dysglycemia.	Baseline, Week 4, 12, 24 and 52
Change From Baseline in Homeostatic Model	Homeostatic Model Assessment (HOMA) beta-cell function, a soluble biomarker of Dysglycemia was determined in fasting blood	Baseline, Week 4, 12, 24 and 52

Assessment (HOMA) Beta-cell Function at Week 4, 12, 24 and 52	samples to evaluate the effect of secukinumab on Dysglycemia.	
Change From Baseline in Homeostatic Model Assessment (HOMA) Insulin Resistance at Week 4, 12, 24 and 52	HOMA insulin resistance, a soluble biomarker of Dysglycemia was determined in fasting blood samples to evaluate the effect of secukinumab on Dysglycemia.	Baseline, Week 4, 12, 24 and 52
Change From Baseline in Hemoglobin A1c (Glycated Hemoglobin) at Week 4, 12, 24 and 52	Hemoglobin A1c (glycated hemoglobin), a soluble biomarker of Dysglycemia was determined in fasting blood samples to evaluate the effect of secukinumab on Dysglycemia.	Baseline, Week 4, 12, 24 and 52
Change From Baseline in Sex Hormone-binding Globulin (SHBG) at Week 4, 12, 24 and 52	Sex hormone-binding globulin (SHBG), a soluble biomarker of Dysglycemia was determined in fasting blood samples to evaluate the effect of secukinumab on Dysglycemia.	Baseline, Week 4, 12, 24 and 52
Change From Baseline in Triglycerides, Total Cholesterol, Low Density Lipoprotein (LDL), High Density	Triglycerides, Total cholesterol, Low density lipoprotein (LDL), High density lipoprotein (HDL), Apolipoprotein A-1 (ApoA-1) and Apolipoprotein B (ApoB), soluble biomarkers of impaired lipid metabolism were determined in fasting blood samples to evaluate the effect of secukinumab on impaired lipid metabolism.	Baseline, Week 4, 12, 24 and 52

Lipoprotein (HDL), Apolipoprotein A-1 (ApoA-1) and Apolipoprotein B (ApoB) at Week 4, 12, 24 and 52		
Change From Baseline in Adiponectin at Week 4, 12, 24 and 52	Adiponectin, a soluble biomarker of impaired lipid metabolism was determined in fasting blood samples to evaluate the effect of secukinumab on systemic inflammation.	Baseline, Week 4, 12, 24 and 52
Change From Baseline in Leptin at Week 4, 12, 24 and 52	Leptin, a soluble biomarker of impaired lipid metabolism was determined in fasting blood samples to evaluate the effect of secukinumab on systemic inflammation.	Baseline, Week 4, 12, 24 and 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
2015-08-04

First Submitted that Met QC Criteria
2015-09-23

First Posted (Estimated)
2015-09-24

Results Reporting Dates

Results First Submitted
2017-04-19

Results First Submitted that Met QC Criteria
2017-04-19

Results First Posted
2017-07-13

Study Record Updates

Last Update Submitted that met QC Criteria
2017-04-19

Last Update Posted
2017-07-13

Last Verified

2017-04

More Information

Terms related to this study

Additional Relevant MeSH Terms

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

Study Documents

No study documents available

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COMPLETED

AIN457 Regimen Finding Study in Patients With Moderate to Severe Psoriasis

ClinicalTrials.gov ID **NCT00941031**

Sponsor Novartis Pharmaceuticals

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

Last Update Posted 2015 08 20

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 Regimen Finding 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: AIN457A
- Drug: AIN457A
- Drug: Placebo

Other Study ID Numbers

- CAIN457A2211
- 2008 007525 39 (EudraCT Number)

Study Start

2009 07

Primary Completion (Actual)

2010 12

Study Completion (Actual)

2010 12

Enrollment (Actual)

404

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

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 at least 18 years of age at time of consent
- Chronic plaque type psoriasis diagnosed for at least 6 months at time of randomization
- At time of 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 and/or
    - phototherapy and/or
    - previous systemic therapy

Exclusion Criteria:

- Patients meeting any of the following criteria will be excluded from entry into the study:
- Forms of psoriasis other than chronic plaque type (e.g., pustular, erythrodermic and guttate psoriasis) at screening or randomization
- Drug induced psoriasis (i.e. new onset or current exacerbation from beta blockers, calcium channel inhibitors or lithium) and randomization
- Ongoing use of prohibited psoriasis treatments (e.g., topical or systemic corticosteroids, UV therapy) at randomization. Washout periods detailed in the study protocol have to be adhered to
- Ongoing use of other prohibited treatments at randomization. Washout periods detailed in the study protocol have to be adhered to. All prior concomitant medications must be on a stable dose for at least four weeks before study drug administration
- Known immunosuppression (e.g., AIDS) at screening and / or randomization
- History or evidence of active tuberculosis at screening. All patients will be tested for tuberculosis status using a blood test (QuantiFERON® TB Gold In Tube). Patients with evidence of latent tuberculosis may enter the trial after sufficient treatment has been initiated according to local regulations.
- Active systemic infections (other than common cold) during the two weeks before randomization (e.g., hepatitis)
- At screening, history or symptoms of malignancy of any organ system (other than history of basal cell carcinoma and / or up to three squamous cell carcinomas of the skin, if successful treatment has been performed, with no signs of recurrence; actinic keratoses, if present at screening, should be treated according to standard therapy before randomization), treated or untreated, within the past 5 years, regardless of whether there is evidence of local recurrence or metastases
- History of congestive heart failure (NYHA functional classification ≥III) at screening and / or randomization

- History of severe hypersensitivity to any human or humanized biological agents (antibody or soluble receptor) at screening and / or randomization
- Any severe, progressive or uncontrolled medical condition at randomization that in the judgment of the investigator prevents the patient from participating in the study
- Pregnant or nursing (lactating) women

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: Induction Single Dose Induction with single injection - "Single": secukinumab (AIN457) 150 mg s.c. administered at Week 1, Baseline through Week 12	Drug: AIN457 • Other Names: ◦ Secukinumab
Experimental: Induction Monthly Dose Induction with monthly injections - "Monthly": secukinumab (AIN457) 150 mg s.c. administered at weeks 1, 5, 9, Baseline through Week 12	Drug: AIN457A • Induction with monthly injections - "Monthly": secukinumab (AIN457) 150 mg s.c. administered at weeks 1, 5, 9 • Other Names: ◦ Secukinumab
Experimental: Induction Early Loading Dose Early loading induction - "Early": secukinumab (AIN457) 150 mg s.c. administered at weeks 1, 2, 3, 5, Baseline through Week 12	Drug: AIN457A • Early loading induction - "Early": secukinumab (AIN457) 150 mg s.c. administered at weeks 1, 2, 3, 5 • Other Names: ◦ Secukinumab

Placebo Comparator: Placebo Dose Placebo administered at weeks 1, 2, 3, 5, 9, Baseline through Week 12	Drug: Placebo • Placebo - "Placebo": Placebo administered at weeks 1, 2, 3, 5, 9

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Efficacy of Three Induction Regimens of AIN457 Administered Subcutaneously in Patients With Moderate to Severe Chronic Plaque-type Psoriasis With Respect to PASI 75 Achievement After 12 Weeks of Treatment, Compared to Placebo.	Number (%) of patients achieving PASI 50, PASI 75, PASI 90, by visit and induction treatment	13 weeks

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame

The Efficacy of Two Maintenance Regimens of AIN457 With Respect to PASI 75 Achievement at Least Once From Week 21 to 29		week 21 to 29
The Efficacy of Three Induction Regimens of AIN457 Administered Subcutaneously With Respect Participants Who Reported Either an IGA 0 or 1 After 12 Weeks of Treatment, Compared to Placebo	The investigator s global assessment (IGA) was used to evaluate overall psoriatic disease, with scores ranging from 0 (clear) to 5 (very severe disease). Treatment success was defined as patients who achieved IGA 0 or 1 and improvement of at least 2 points on the IGA scale compared to baseline. The IGA rating score for involvement of hands and feet ranged from 0 (clear) to 4 (severe).	13 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
2009-07-16

First Submitted that Met QC Criteria
2009-07-16

First Posted (Estimated)
2009-07-17

Results Reporting Dates

Results First Submitted
2015-01-30

Results First Submitted that Met QC Criteria
2015-03-23

Results First Posted (Estimated)
2015-03-27

Study Record Updates

Last Update Submitted that met QC Criteria
2015-07-30

Last Update Posted (Estimated)
2015-08-20

Last Verified
2015-03

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
Immunologic Factors
Physiological Effects of Drugs
Antibodies, Monoclonal

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

Controlled Study of Humira in Subjects With Chronic Plaque Psoriasis of the Hands and/or Feet

ClinicalTrials.gov ID **NCT00735787**

Sponsor Abbott

Information provided by Abbott

Last Update Posted 2010 11 01

Study Details Tab

Study Overview

Brief Summary

Evaluate the efficacy and safety of a 16 week course of Humira (adalimumab) compared to placebo in adults with chronic plaque psoriasis of the hands and/or feet and the sustainability of response for 12 additional weeks.

Feedback

Official Title

Controlled Study of Humira in Subjects With Chronic Plaque Psoriasis of the Hands and/or Feet

Conditions

Psoriasis

Intervention / Treatment

- Biological: Placebo
- Biological: Adalimumab

Other Study ID Numbers

- M10 405

Study Start

2008 08

Primary Completion (Actual)

2009 09

Study Completion (Actual)

2009 09

Enrollment (Actual)

81

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)

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

Arkansas Locations

Little Rock, Arkansas, United States, 72205
Site Reference ID/Investigator# 10168

California Locations

Bakersfield, California, United States, 93309
Site Reference ID/Investigator# 10005



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:

- Adult with Diagnosis of chronic plaque psoriasis of the Hands and Feet for at least 6 months, with a PGA >/=3 and candidates for systemic therapy;
- Patients in good general health
- Able to self administer injections
- Negative chest x ray (CXR) and purified protein derivative (PPD) test, unless willing to start anti tuberculosis (TB) prophylaxis

Exclusion Criteria:

- Previous treatment with HUMIRA®
- Required mediation stability or washouts for: systemic corticosteroids (28 days), other investigational agent, other systemic therapies for psoriasis, ultraviolet B (UVB), psoralen with UVA (PUVA)
- Other active skin diseases or skin infections
- Diagnosis of palmoplantar pustulosis; erythrodermic psoriasis, pustular psoriasis, medication induced or exacerbated psoriasis or new onset of guttate psoriasis
- Evidence of dysplasia or history of malignancy (Other than a successfully treated non metastatic cutaneous squamous cell, basal cell carcinoma or localized carcinoma in situ of the cervix);
- History of listeriosis, histoplasmosis, chronic or active Hepatitis B infection, human immunodeficiency virus (HIV) infection, immunodeficiency syndrome, chronic recurring infections or active tuberculosis (TB);
- History of moderate to severe congestive heart failure,
- Recent cerebrovascular accident and any other condition which, in the opinion of the investigator, would put the subject at risk;
- History of central nervous system (CNS) demyelinating disease or neurologic symptoms suggestive of CNS demyelinating disease;
- History of clinically significant drug or alcohol abuse in the last 12 months;
- Infection(s) requiring treatment with intravenous (IV) antibiotics, IV antivirals, or IV antifungals within 30 days prior to Baseline or oral antibiotics, oral antivirals, or oral antifungals within 14 days prior to Baseline;
- Known hypersensitivity to the excipients of HUMIRA® as stated in the label;
- Female subjects who are pregnant or breast feeding or considering becoming pregnant during the study.
- Prior exposure to Tysabri® (natalizumab)

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: Placebo/Adalimumab Loading dose of 2 placebo injections at Week 0 and placebo injections every other week (eow) from Week 1 through Week 15. In second period of study, subjects who continued in the study received 80 mg adalimumab at Week 16 followed by open-label 40 mg adalimumab eow from Week 17 to Week 27.	Biological: Placebo • Loading dose of 2 placebo subcutaneous (SC) injections (0.8 ml) at Week 0 followed by 1 injection SC eow from Week 1 to Week 15.In second period of study, subjects who continued in the study received 80 mg adalimumab at Week 16 followed by open-label 40 mg adalimumab eow from Week 17 to Week 27. Biological: Adalimumab • Loading dose of 80 mg adalimumab SC (two 40 mg injections) followed by 40 mg adalimumab SC eow. • Other Names: ◦ Humira ◦ ABT-D2E7
Active Comparator: Adalimumab 80 mg adalimumab loading dose at Week 0 and 40 mg adalimumab eow from Weeks 1 through 15. For subjects who continued in the second period of the study, subjects received 2 placebo injections at Week 16 to maintain the blind.	Biological: Adalimumab • Loading dose of 80 mg adalimumab SC (two 40 mg injections) followed by 40 mg adalimumab SC eow. • Other Names: ◦ Humira ◦ ABT-D2E7

Open-label 40 mg adalimumab eow was administered from Week 17 through Week 27.	

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Subjects With Physicians Global Assessment of Psoriasis (PGA) of Clear or Almost Clear at Week 16	Number of subjects achieving a PGA of clear (representing no signs of plaque psoriasis) or almost clear (representing just perceptible erythema and scaling) at Week 16. The PGA is a 5-point scale used to measure the severity of disease at the time of the physicians evaluation of the subject. The degree of overall severity is rated as follows: 0-Clear, 1-Almost clear, 2-Mild, 3-Moderate, and 4-Severe.	Week 16

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Mean Change From Baseline in Erythema, Scaling, Induration, and Fissuring (ESIF)	Severity of each sign of ESIF was assessed using a 4-point scale (0 = clear, 1 = mild, 2 = moderate, and 3 = severe). The ESIF was calculated by adding the scores for the 4 signs for the two soles and two palms, for a total range from 0 (no disease) to 48 points (most severe condition). A decrease from Baseline in ESIF indicates improvement.	Baseline and Weeks 2, 4, 8, 12, 16, 20, 24, 28
Mean Change From Baseline	Severity of each sign of ESIF was assessed using a 4-point scale (0 = clear, 1 = mild, 2 = moderate, and 3 = severe). The ESIF was calculated by	Baseline and Weeks

in ESIF for Palms	adding the scores for the 4 signs for the palms of the hands, yielding a total range from 0 (no disease) to 24 points (most severe condition) for the palms. A decrease from Baseline in ESIF indicates improvement.	2, 4, 12, 16, 20, 24, and 28
Mean Change From Baseline in ESIF for Soles	Severity of each sign of ESIF was assessed using a 4-point scale (0 = clear, 1 = mild, 2 = moderate, and 3 = severe). The ESIF was calculated by adding the scores for the 4 signs for the soles of the feet, yielding a total range from 0 (no disease) to 24 points (most severe condition) for the soles. A decrease from Baseline in ESIF indicates improvement.	Baseline and Weeks 2, 4, 8, 12, 16, 20, 24, 28
Number of Subjects With Moderate Improvement in ESIF From Baseline	Number of subjects that achieved > 50% reduction from Baseline in ESIF.	Baseline and Weeks 2, 4, 8, 12, 16, 20, 24, 28
Number of Subjects With Marked Improvement in ESIF From Baseline	Number of subjects that achieved > 75% reduction from Baseline in ESIF	Baseline and Weeks 2, 4, 8, 12, 16, 20, 24, 28
Mean Change From Baseline in Nail Psoriasis Severity Index (NAPSI)	For subjects with psoriasis nail involvement at Baseline, the target fingernail (most severely involved fingernail at Baseline) was assessed for NAPSI throughout the study. NAPSI ranges from 0 (no nail psoriasis) to 8 (most severe nail psoriasis).	Baseline and Weeks 8, 16, and 28
Number of Subjects With	Number of subjects achieving a PGA of clear (representing no signs of plaque psoriasis),	Baseline and

Physicians Global Assessment of Psoriasis (PGA) of Clear, Almost Clear, or Mild	almost clear (representing just perceptible erythema and scaling), or mild (representing light pink erythema with minimal scaling and with or without pustules). The PGA is a 5-point scale used to measure the severity of disease at the time of the physicians evaluation of the subject. The degree of overall severity is rated as follows: 0-Clear, 1-Almost clear, 2-Mild, 3-Moderate, and 4-Severe.	Weeks 2, 4, 8, 12, 16, 20, 24, and 28
Number of Subjects With PGA of Clear or Almost Clear	Number of subjects achieving a PGA of clear (representing no signs of plaque psoriasis) or almost clear (representing just perceptible erythema and scaling). The PGA is a 5-point scale used to measure the severity of disease at the time of the physicians evaluation of the subject. The degree of overall severity is rated as follows: 0-Clear, 1-Almost clear, 2-Mild, 3-Moderate, and 4-Severe.	Baseline and Weeks 2, 4, 8, 12, 20, 24, and 28
Number of Subjects With PGA of Clear	Number of subjects achieving a PGA of clear (representing no signs of plaque psoriasis). The PGA is a 5-point scale used to measure the severity of disease at the time of the physicians evaluation of the subject. The degree of overall severity is rated as follows: 0-Clear, 1-Almost clear, 2-Mild, 3-Moderate, and 4-Severe.	Baseline and Weeks 2, 4, 8, 12, 16, 20, 24, and 28
Number of Subjects With Psoriasis Area and Severity Index (PASI) 50	Number of subjects who achieved 50% or greater improvement from baseline PASI. The PASI scale is from 0 (no psoriasis) to 72 (complete erythroderma of the severest possible degree).	Baseline and Weeks 16 and 28
Number of Subjects With PASI 75	Number of subjects who achieved 75% or greater improvement from baseline PASI. The PASI scale is from 0 (no psoriasis) to 72 (complete erythroderma of the severest possible degree).	Baseline and Weeks 16 and 28

Number of Subjects With PASI 90	Number of subjects who achieved 90% or greater improvement from baseline PASI. The PASI scale is from 0 (no psoriasis) to 72 (complete erythroderma of the severest possible degree).	Baseline and Weeks 16 and 28
Number of Subjects With PASI 100	Number of subjects who achieved 100% improvement from baseline PASI. The PASI scale is from 0 (no psoriasis) to 72 (complete erythroderma of the severest possible degree).	Baseline and Weeks 16 and 28
Mean Change From Baseline in Dermatology Life Quality Index (DLQI)	The DLQI consists of 10 questions and is scored from 0 (total lack of impairment) to 30 (life is very much impaired). A decrease in DLQI indicates improvement.	Baseline and Weeks 2, 8, 16, and 28
Number of Subjects Achieving a DLQI of 0	Number of subjects achieving a DLQI score of 0, indicating total lack of impairment. The DLQI consists of 10 questions and is scored from 0 to 30 (life is very much impaired). A decrease in DLQI indicates improvement.	Baseline and Weeks 2, 8, 16, and 28
Mean Change From Baseline in Visual Analog Scale (VAS) for Psoriasis and Psoriatic Arthritis Pain	On one single VAS, subjects assessed their pain due to psoriasis (and psoriatic arthritis, if applicable). Mean change in psoriasis and psoriatic arthritis pain from Baseline as measured by a VAS from 0 (no pain) to 100 (pain as bad as it could be).	Baseline and Weeks 16 and 28
Mean Change From Baseline in Work Productivity and Activity Impairment Questionnaire:	WPAI:PSO assesses the effect on the subject s ability to work and perform regular activities in 4 areas: % work time (in hours) missed due to psoriasis, % impairment while working (on a scale from 0 [psoriasis having no effect] to 10 [psoriasis completely prevented subject from working]), % overall work impairment (on a scale	Baseline and Weeks 8, 16, and 28

Psoriasis (WPAI:PSO)	from 0 [psoriasis having no effect] to 10 [psoriasis completely prevented subject from working]), and % activity impairment (on a scale from 0 [psoriasis having no effect on daily activities] to 10 [psoriasis completely prevented subject from doing daily activities]).	
Mean Change From Baseline in Patient Health Questionnaire (PHQ-9)	The PHQ-9 consists of 9 questions that assess how often over the past 2 weeks subjects had signs or symptoms of depression (0=not at all, 1=several days, 2=more than half days, and 3=nearly every day). The PHQ-9 is the sum of the scores from the 9 questions for a total range from 0 (not depressed at all) to 27 (depressed nearly every day).	Baseline and Weeks 2, 8, 16, and 28
Number of Subjects With Difficulties According to PHQ-9	Based on the 9 questions of the PHQ-9, if subjects indicated any problems (PHQ-9 score > 0), the difficulty to do work, take care of things at home, and get along with people (question 10 of the PHQ) were assessed (not difficult at all, somewhat difficult, very difficult, and extremely difficult).	Baseline and Weeks 2, 8, 16, and 28

Collaborators and Investigators

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

Sponsor

Abbott

Collaborators

No information provided

Investigators

- Study Director: Martin Okun, MD, Abbott

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
2008-08-13

First Submitted that Met QC Criteria
2008-08-14

First Posted (Estimated)
2008-08-15

Results Reporting Dates

Results First Submitted
2010-09-01

Results First Submitted that Met QC Criteria
2010-10-11

Results First Posted (Estimated)
2010-11-01

Study Record Updates

Last Update Submitted that met QC Criteria
2010-10-11

Last Update Posted (Estimated)
2010-11-01

Last Verified
2010-10

More Information

Terms related to this study

Additional Relevant MeSH Terms

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

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by Abbott

prescribing information (http://www.humira.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

Effects of Desoximetasone Spray 0.25% on Moderate to Severe Plaque Psoriasis

ClinicalTrials.gov ID NCT01206387

Sponsor Taro Pharmaceuticals USA

Information provided by Taro Pharmaceuticals USA (Responsible Party)

Last Update Posted 2017 06 05

Study Details Tab

Study Overview

Brief Summary

efficacy study in patients with moderate to severe plaque psoriasis.

Detailed Description

Feedback

A Double Blind, Vehicle Controlled, Randomized, Parallel Design, Multiple Site Clinical Study to Evaluate the Efficacy and Safety of Desoximetasone 0.25% Topical Spray in Patients with Moderate to Severe Plaque Psoriasis

Official Title

A Double Blind, Vehicle Controlled, Randomized, Parallel Design, Multiple Site Clinical Study to Evaluate the Efficacy and Safety of Desoximetasone 0.25% Topical Spray in Patients With Moderate to Severe Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Desoximetasone Spray 0.25%
- Drug: placebo comparator

Other Study ID Numbers

- DSXS 0808

Study Start

2010 08

Primary Completion (Actual)

2010 12

Study Completion (Actual)

2011 01

Enrollment (Actual)

120

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: 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.

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:

- Male or non pregnant, non lactating female 18 years of age or older.
- Have a definite clinical diagnosis of stable plaque psoriasis involving ≥ 10% of the body surface area (BSA).
- Have a combined total lesion severity score (TLSS) of ≥ 7 for the Target Lesion.
- Have a plaque elevation score ≥ 3 of (moderate) for the Target Lesion.
- The Target Lesion must have an area of at least 5 cm^2.
- Have a Physicians Global Assessment (PGA) score of 3 (moderate) or 4 (severe) at baseline for the overall disease severity.

Exclusion Criteria:

- Patient has current diagnosis of other types of psoriasis other than stable plaque psoriasis (i.e. acute, guttate, erythrodermic, exfoliative or pustular psoriasis) or has psoriasis of any kind of the face or scalp that will require active treatment during the study. Nonprescription antipsoriatic shampoos will be allowed during the study when applied solely to the scalp.
- 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 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. The use of inhaled or intranasal corticosteroids is acceptable as long as usage has been stable for at least 2 weeks prior to the first dose of study drug and will be continued during the study.
- 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. Nonprescription antipsoriatic shampoos used only on the scalp will be allowed during the study.
- Receipt of any drug as part of a research study within 30 days prior to first dosing.

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: active product Desoximetasone Spray 0.25%	Drug: Desoximetasone Spray 0.25% • Desoximetasone topical spray 0.25% administered to affected area twice a day for 28 days • Other Names: ◦ Desoximetasone
Placebo Comparator: placebo comparator vehicle	Drug: placebo comparator • Placebo administered to affected area twice a day for 28 days • Other Names: ◦ vehicle

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Clinical Success	A patient is considered a Clinical Success if the Physician s Global Assessment (PGA) is 0 (clear) or 1 (almost clear).	28 days
Treatment Success	A patient is considered a Treatment Success for the Target Lesions if the target lesion has a score of 0 or 1 on the Target Lesion Severity Score (TLSS)for each of each of the three signs and symptoms (erythema, scaling and plaque elevation).	28 days

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Mean Change From Baseline in Physician Global Assessment (PGA) Score at Day 28 Using ITT.	In the Physician Global Assessment of psoriasis is a score based on physician assessment of overall disease severity for all lesions assessed at baseline and at Day 28. The PGA score range: from 0 (Clear=No Psoriatic lesions, i.e. no plaque formation; no erythema, no induration, no scaling) to 5 (Very Severe=Coarse scaling with pronounced cracking and fissures. Erythema is dark red with induration. Plaques are markedly elevated with sharp and hard edges). The first evaluation was for the change from baseline in PGA, using a two-sided, α = 0.05 level of significance. If superiority of the test product over its vehicle was demonstrated ($p<0.05$), then PGA change from baseline values was examined.	Baseline and day 28
Mean Change From Baseline in Total Lesion Severity Scale (TLSS) (ITT)	Mean Change from Baseline in Lesion Severity Scale-TLSS (ITT) TLSS of psoriasis is a combined score based on physician assessment of disease severity for the Target Lesion assessed at baseline and at Day 28. The TLSS combined score included summary of individually scored induration (as 0=Clear or 1=Almost Clear, or 2=Mild, or 3=Moderate, or 4=Severe, or 5=Very Severe), erythema (as 0=Clear or 1=Almost Clear, or 2=Mild, or 3=Moderate, or 4=Severe, or 5=Very Severe), and scaling (as 0=Clear or 1=Almost Clear, or 2=Mild, or 3=Moderate, or 4=Severe, or 5=Very Severe). To be eligible for inclusion in the study, the combined score of all three signs for the Target Lesion must total at least 7 and the patient must have at least a score of 3=Moderate for plaque elevation	Baseline and day 28

	The first evaluation was for the change from baseline in TLSS, using a two-sided, α = 0.05 level of significance.	
Mean Change From Baseline in Percent Body Surface Area (%BSA) Affected at Day 28	Mean Change from Baseline in percent body surface area (%BSA) affected by Psoriasis The 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 For the %Body Surface Area Affected the "Rule of Nine" was be used. Change From Baseline in Percent Body Surface Area i.e., difference of base percent values [Percent Body Surface Area at 28 days - Percent Body Surface Area at Baseline].	Baseline and day 28

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

- Study Chair: Novum Pharmaceutical Research Services, http://www.novumprs.com/contact

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
2010-09-20

First Submitted that Met QC Criteria
2010-09-20

First Posted (Estimated)
2010-09-21

Results Reporting Dates

Results First Submitted
2014-01-22

Results First Submitted that Met QC Criteria
2014-07-14

Results First Posted (Estimated)
2014-08-07

Study Record Updates

Last Update Submitted that met QC Criteria
2017-05-03

Last Update Posted
2017-06-05

Last Verified
2017-05

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
Desoximetasone

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

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).

COMPLETED

A Study to Evaluate Safety and Efficacy of Infliximab in Chinese Participants With Moderate to Severe Plaque-type Psoriasis

ClinicalTrials.gov ID NCT01177800

Sponsor Xian Janssen Pharmaceutical Ltd.

Information provided by Xian Janssen Pharmaceutical Ltd. (Responsible Party)

Last Update Posted 2014 09 12

Study Details Tab

Study Overview

Brief Summary

Feedback

The purpose of this study is to determine the superiority and efficacy of infliximab induction therapy in chinese participants with moderate to severe plaque type psoriasis (scaly skin rash) compared with placebo (an inactive substance that is compared with a drug to test whether the drug has a real effect in a clinical trial).

Detailed Description

This is a double blind (neither physician nor participant knows the treatment that the participant receives), multicenter (when more than one hospital or medical school team work on a medical research study) and placebo controlled study of infliximab in participants with moderate to severe plaque type psoriasis. All the eligible participants will be randomly assigned to infliximab and placebo groups. The infliximab group will receive 5 milligram per kilogram (mg/kg) infliximab infusions (a fluid or a medicine delivered into a vein by way of a needle) intravenously (into a vein) at Week 0, 2 and 6 in the induction treatment phase followed by maintenance regimen of the intervention every 8 weeks up to 26 weeks. Placebo infusions will also be given at Week 10, 12 and 16. The placebo group will receive placebo infusion at Week 0, 2, 6, 14 and 22. At Week 10, participants in placebo group will then receive infliximab induction therapy. Efficacy of the participants will primarily be evaluated by percentage of participants who achieve a Psoriasis Area and Severity Index 75 (PASI) response at Week 10. Participants safety will be monitored throughout the study.

Official Title

A Phase 3, Multicenter, Randomized, Double blind, Placebo controlled Study Evaluating the Efficacy and Safety of Infliximab in the Treatment of Chinese Subjects With Moderate to Severe Plaque type Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Placebo
- Drug: Infliximab

Other Study ID Numbers

- CR013804
- REMICADEPSO3004

Study Start

2009 02

Primary Completion (Actual)

2010 02

Study Completion (Actual)

2010 09

Enrollment (Actual)

129

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.

China

- Beijing, China
- Beijng, China
- Dalian, China

Jinan, China

Nanjing, China

Shanghai, China

Xi'An, China

Xian. China

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:

- The body weight should be less than or equal to 80 kilogram
- Participants who had a diagnosis of plaque type psoriasis (scaly skin rash) greater than or equal to 6 months before Screening (participants with concurrent psoriatic arthritis [joint pain] may be enrolled)
- Participants who had plaque type psoriasis covering greater than or equal to 10 percent of total body surface area, Psoriasis Area Severity Index (PASI) score greater than or equal to 12 at Screening and at the Baseline
- Participants who are candidates for systemic treatment of psoriasis
- Females of childbearing potential and all men must be using adequate birth control measures and agree to use these measures and should not become pregnant (carrying an unborn baby) or plan to become pregnant up to 6 months after receiving last infusion of study drug

Exclusion Criteria:

- Participants who have nonplaque forms of psoriasis (for example, erythrodermic, guttate, or pustular), or have current drug induced psoriasis (for example, a new onset of psoriasis or an exacerbation of psoriasis from beta blockers, calcium channel blockers, or lithium)
- Participants who are pregnant, nursing or planning to become pregnant within one year while enrolled in the study
- Participants who had previous treatment with infliximab
- Participants who have received agents targeted at reducing tumour necrosis factor or any biologic treatment within the previous 3 months
- Participants who have used any investigational drug within the previous 4 weeks or 5 times the half life of the investigational agent, whichever is longer

Ages Eligible for Study

18 Years to 65 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: Infliximab 5 milligram per kilogram (mg/kg) infusion (a fluid or a medicine delivered into a vein by way of a needle) of infliximab administered intravenously (into a vein) at Week 0, 2 and 6 followed by maintenance regimen of 5 mg/kg infliximab at Week 14 and 22. Placebo (an inactive substance that is compared with a drug to test whether the drug has a real effect in a clinical trial infusion), matched to infliximab will be given at Week 10, 12 and 16. Total duration of treatment will be 26 weeks.	Drug: Placebo • Placebo matched to infliximab given at Weeks 10, 12 and 16 in Infliximab arm and at Weeks 0, 2 and 6 in Placebo arm Drug: Infliximab • 5 mg/kg infusion given intravenously at Week 0,2,6 (induction treatment phase) and at Week 14 and 22 in maintenance phase in infliximab arm and at Week 12 and 16 in Placebo arm. • Other Names: ◦ Remicade
Experimental: Placebo Placebo infusion, matched to infliximab will be given intravenously at Week 0, 2 and 6. At Week 10,	Drug: Placebo • Placebo matched to infliximab given at Weeks 10, 12 and 16 in Infliximab arm and at Weeks 0, 2 and 6 in Placebo arm Drug: Infliximab

12 and 16, participants will receive 5 mg/kg infliximab intravenously. Placebo infusion will be again given at Week 14 and 22. Total duration of treatment will be 26 weeks.	• 5 mg/kg infusion given intravenously at Week 0,2,6 (induction treatment phase) and at Week 14 and 22 in maintenance phase in infliximab arm and at Week 12 and 16 in Placebo arm. • Other Names: ◦ Remicade

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Who Achieved a Greater Than Equal to 75 Percent Response in Psoriasis Area and Severity Index (PASI)	The PASI score is based on the assessment of the erythema (e), induration (I), scaling (S), and the body is divided into 4 regions head, trunk, upper extremities, lower extremities. The assessment was done on 4-point scale (where, 0 = none, 1 = slight, 2 = moderate, 3 = severe, and 4 = very severe). The total possible score ranges from 0 (no disease) to 72 (maximal disease). Participants with no less than 75 percent relative Baseline improvement in the PASI scores are considered to be PASI 75 responders.	Week 10

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Baseline in Dermatology Life Quality Index (DLQI) at Week 10	The DLQI is a dermatology-specific quality of life (QOL) instrument designed to assess impact of disease on a participants QOL. It is a 10-item questionnaire that, in addition to evaluating overall, QOL can be used to assess 6 different aspects: symptoms and feelings, daily activities,	Baseline and Week 10

	leisure, work or school performance, personal relationships and treatment. Questions scored on a 4-point Likert scale: 0 (not relevant), 1 (a little), 2 (a lot), and 3 (very much). Scores of individual items (0-3) were added to yield a total score (0-30); higher score = greater impairment of participants QOL.	
Percentage of Participants With Static Physician Global Assessment (PGA) Score Less Than Equal to 1 at Week 10	The Static physician global assessment (PGA) determines psoriasis lesions overall at given time point. Overall lesions graded for I (0= no evidence of plaque elevation to 5= severe plaque elevation), E (0 = no evidence of E, hyperpigmentation may be present to 5=dusky to deep red coloration), S (0 = no evidence of S to 5 = severe; very thick tenacious scale predominates). Sum of 3 scales divided by 3 gives final PGA score. Range for final score is 0 = cleared, except for residual discoloration, 1 = minimal, 2 = mild, 3=moderate, 4= marked and 5= severe; Scores should be rounded to the nearest whole number. If total ≤1.49, score = 1; if total≥ 1.50, score = 2. Percentage of participants with static PGA score <= 1 at week 10 were reported.	Week 10

Other Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Baseline in Dermatology Life Quality Index (DLQI) at Week 26	The DLQI is a dermatology-specific QOL instrument designed to assess impact of disease on a participants QOL. It is a 10-item questionnaire that, in addition to evaluating overall, QOL can be used to assess 6 different aspects: symptoms and feelings, daily activities, leisure, work or school performance, personal relationships and treatment. Questions scored on a 4-point Likert scale: 0 (not relevant), 1 (a little), 2 (a lot), and 3 (very much). Scores of individual items (0-3) were added to yield a total	Baseline and Week 26

	score (0-30); higher score = greater impairment of participants QOL.	
Number of Participants With Adverse Events (AEs) as a Measure of Safety and Tolerability	The AE is defined as any untoward medical occurrence in a participant participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. A serious adverse event (SAE) was an AE resulting in any of following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); significant disability; congenital (occurred before birth, due to parent s genetic input) anomaly.	Baseline up to end of study (Week 26)

Collaborators and Investigators

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

Sponsor

Xian-Janssen Pharmaceutical Ltd.

Collaborators

No information provided

Investigators

- Study Director: Xian Janssen Pharmaceutical Ltd., China Clinical Trial, Xian Janssen Pharmaceutical Ltd.

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
2010-08-05

First Submitted that Met QC Criteria
2010-08-05

First Posted (Estimated)
2010-08-09

Results Reporting Dates

Results First Submitted
2013-06-06

Results First Submitted that Met QC Criteria
2014-02-17

Results First Posted (Estimated)
2014-03-17

Study Record Updates

Last Update Submitted that met QC Criteria
2014-09-04

Last Update Posted (Estimated)
2014-09-12

Last Verified
2014-09

More Information

Terms related to this study

Keywords Provided by Xian-Janssen Pharmaceutical Ltd.

Psoriasis
Infliximab
Remicade

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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TERMINATED

Recruiting complete and administrative termination

Mechanistically-based Optimization of UV Radiation Therapy in Psoriasis

ClinicalTrials.gov ID **NCT00470392**

Sponsor VA Office of Research and Development

Information provided by VA Office of Research and Development (Responsible Party)

Last Update Posted 2016 10 05

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is 1) to determine whether Imiquimod or Steroid pretreatment modifies UVB laser light response resulting in increased cell death compared to UVB laser light alone; 2) to determine if pretreatment of psoriatic lesions with Imiquimod or Steroid prior to UVB laser light

Feedback

exposure selectively effects various T cell functions; 3) to determine clinical results from the Imiquimod/Steroid/UVB laser light and correlate those changes with immuno histochemical changes in the skin; and 4) to determine if single high dose lesion limited UVB laser light intervention combined with Imiquimod or Steroid influences T cell changes

Detailed Description

The characteristic lesion of psoriasis is a sharply demarcated erythematous papule or plaque with excessive scaling due to hyperproliferating keratinocytes, infiltrating granulocytes, and a dense mononuclear infiltrate with activated T cells. To date, no one mechanism has been explanatory for the panoply of changes that occur in both the dermis and epidermis of psoriasis patients. Several key findings have shown that cutaneous T cells play a key role in the propagation of the disease; memory type T cells home to the skin, specifically due to expression of cutaneous lymphocyte antigen (CLA), and are the main effector cells in psoriatic tissue responsible for the production of cytokines that result in exacerbated cutaneous inflammation. T cell recruitment is thought to occur in psoriasis, in part, as a result of cytokine and chemokine release from keratinocytes, macrophages, and endothelial cells. CLA positive T cells migrate into the tissues where memory effector T cells are activated and expand. This migration is critical to maintenance of the psoriasis lesions, because anti LFA 1 antibodies (efalizumab) are effective in treating psoriasis, resulting in blood lymphocytosis and tissue depletion of T cells. Despite many years of using UVB phototherapy in the treatment of psoriasis, its mechanism of action is based mainly on in vitro exposures of isolated cells and on extrapolations from UV effects on normal skin, with little direct data from lesional skin.

Previously, our studies determined optimal single efficacious dose using the Excimer laser, refined the mechanism of UVB action in psoriasis, developed key cytokine quantitative meth ods to assess targeted mRNA levels in psoriatic tissue after treatment, demonstrated that regulatory T cells from psoriasis tissue and blood appear to have a functional defect, and demonstrated that UVA component of solar radiation is a critical and significant contributor to UV induced in vivo immuno suppression. All of these previous findings lead us to our current hypothesis that direct selective apoptotic effects on the T mem/Teff cells may result in decreased APC activation and IL 12 over riding of Treg suppression and a re balanced Tre:Tmem/eff cell ratio which in turn may have a sustained remittive effect (high duration multi month clearing of a psoriasis lesion after a single UVB laser light treatment.)

Official Title

Mechanistically based Optimization of UV Radiation Therapy in Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Imiquimod
- Drug: Clobetasol

Other Study ID Numbers

- IMMB 004 06S

Study Start

2007 05

Primary Completion (Actual)

2010 07

Study Completion (Actual)

2012 07

Enrollment (Actual)

9

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: Clobetasol propionate (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Clobetasol+propionate) Imiquimod (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Imiquimod)

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

Ohio Locations

Cleveland, Ohio, United States, 44106
University Hospital Case Medical Center

Cleveland, Ohio, United States, 44106
VA Medical Center, Cleveland

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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:

- The presence of plaque type psoriasis in areas of the trunk, buttocks, or extremities that are amenable to biopsy and evaluable disease in at least 2 cm target treatment sites separated by 1 cm
- Age 18 80, both genders, all ethnicities
- No contraindications to phototherapy or biopsy procedures
- No topical steroid, tar, phototherapy, Vitamin D, or retinoid therapy to target lesions for at least 1 week prior to the study
- No systemic psoriasis therapy for at least four weeks prior to the study
- Able to give informed consent under IRB approval procedures

Exclusion Criteria:

- Photosensitivity disorders
- Active untreated diseases or medication usage which may interfere with UVB, wound healing, or immune function
- Hypersensitivity to local anesthetic
- Inability to provide informed consent
- Pregnancy and /or lactating

Ages Eligible for Study

18 Years to 80 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

Allocation : Non Randomized
Interventional Model : Factorial Assignment
Masking : Single (Participant)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Other: Imiquimod Each study subject served as his/her own control. For this arm of the study, topical vehicle was applied to one plaque for 5 days. Imiquimod (5% topical cream) was applied to two psoriasis plaques for 5 days. Skin biopsies were taken from half of each of the 3 plaques at specific time points after completion of topical pre-treatment. The other half of the plaques were exposed to UVB light (via Excimer laser). Biopsies were subsequently taken at a specified time point.	Drug: Imiquimod • Each study subject served as his/her own control. For this arm of the study, topical vehicle was applied to one plaque for 5 days. Imiquimod (5% topical cream) was applied to two psoriasis plaques for 5 days. Skin biopsies were taken from half of each of the 3 plaques at specific time points after completion of topical pre-treatment. The other half of the plaques were exposed to UVB light (via Excimer laser). Biopsies were subsequently taken at a specified time point. • Other Names: ◦ Aldara
Other: Clobetasol Each study subject served as his/her own control. For this arm of the study, topical vehicle was applied to one plaque for 5 days. Clobetasol propionate 0.05% was applied to	Drug: Clobetasol • Each study subject served as his/her own control. For this arm of the study, topical vehicle was applied to one plaque for 5 days. Clobetasol propionate 0.05% was applied to two psoriasis plaques for 5 days. Skin biopsies were taken from half of each of the 3 plaques at specific time points after completion of topical pre-treatment.

two psoriasis plaques for 5 days. Skin biopsies were taken from half of each of the 3 plaques at specific time points after completion of topical pre-treatment. The other half of the plaques were exposed to UVB light (via Excimer laser). Biopsies were subsequently taken at a specified time point.	The other half of the plaques were exposed to UVB light (via Excimer laser). Biopsies were subsequently taken at a specified time point. • Other Names: ◦ Temovate

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Subjects With Elevated MyxA	Lesions were treated with either Imiquimod or Clobetasol cream. Lesions were subsequently treated with UVB and biopsied. From the biopsy samples obtained from the Imiquimod arm, quantitative PCR was performed to measure levels of Myx A, an imiquimod response gene.	Biopsy samples for analysis were taken 1 hour post UVB treatment

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Subjects With	The PASI is a disease burden measure that integrates area, erythema, thickness and scale	2 weeks after

Improvement in Lesional Psoriasis Area and Assessment (PASI) Score After Imiquimod and UVB Treatment	of each target lesion. The severity score for each region is calculated by adding the scores for redness, thickness and scale (each of which are graded from 0 to 4). The maximum severity score is 12. The higher the PASI, the worse the disease. Thus, an improvement in PASI score is a lower score than the pre-treatment PASI.	Imiquimod and UVB
Number of Subjects With a 1.5 Fold Increase in mRNA Expression of GRAMD1A and DMXL2	Based upon upregulated mRNA expression of MyxA in 1 out of 7 patients treated with Imiquimod, a list of alternative target genes responsive to Imiquimod was generated. The target mRNAs examined included GRAMD1A, IL2RA, TGHD1, DMXL2. The target gene was consider upregulated if there was a 1.5 fold increase in the mRNA expression of the target gene.	Biopsy samples for analysis were taken 1 hour post UVB treatment

Collaborators and Investigators

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

Sponsor

VA Office of Research and Development

Collaborators

- University Hospitals Cleveland Medical Center

Investigators

- Principal Investigator: Kevin D Cooper, MD, VA Medical Center, Cleveland

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
2007-05-04

First Submitted that Met QC Criteria
2007-05-04

First Posted (Estimated)
2007-05-07

Results Reporting Dates

Results First Submitted
2013-09-26

Results First Submitted that Met QC Criteria
2013-12-19

Results First Posted (Estimated)
2014-02-12

Study Record Updates

Last Update Submitted that met QC Criteria
2016-10-03

Last Update Posted (Estimated)
2016-10-05

Last Verified

2016-10

More Information

Terms related to this study

Keywords Provided by VA Office of Research and Development

Erythema
optimization
Papule
Plaque
pretreatment
T cells
UVB laser light
psoriasis
topical administration

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Adjuvants, Immunologic
Immunologic Factors
Physiological Effects of Drugs
Antineoplastic Agents
Interferon Inducers
Anti Inflammatory Agents
Glucocorticoids
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Clobetasol
Imiquimod

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by VA Office of Research and Development

The National Institute of Arthritis, Musculoskeletal, and Skin Diseases website providing fast facts on health topics, including psoriasis
(http://www.niams.nih.gov/Health_Info/psoriasis/)

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 Study to Evaluate the Safety and Efficacy of Efalizumab in Adult Patients With Moderate to Severe Plaque Psoriasis With Involvement of the Scalp (SCALP)

ClinicalTrials.gov ID **NCT00669214**

Sponsor Genentech, Inc.

Information provided by Genentech, Inc. (Responsible Party)

Last Update Posted 2017 06 06

Study Details Tab

Study Overview

Brief Summary

Feedback

This was a Phase IV randomized, double blind, placebo controlled study designed to evaluate the safety and efficacy of subcutaneous efalizumab in adult patients (18 years of age and older) with chronic moderate to severe plaque psoriasis with involvement of the scalp who had no previous exposure to efalizumab. The study consisted of a screening period, a double blind treatment period, an open label treatment period, and an observation/follow up period. The study enrolled 100 patients. 11 patients were excluded from all analyses because of data issues.

Detailed Description

- Baselines for Raptiva group and placebo group at Day 84 are the same. The baseline is Day 0.
- Baselines for Raptiva group and placebo group at Day 168 are different. The baseline for Raptiva group at Day 168 is Day 0, but the baseline for Placebo group at Day 168 is Day 84

Official Title

A Phase IV Randomized, Double Blind, Placebo Controlled Study to Evaluate the Safety and Efficacy of 1.0 mg/kg Efalizumab in Adult Patients With Moderate to Severe Plaque Psoriasis With Involvement of the Scalp

Conditions

Psoriasis

Intervention / Treatment

- Drug: efalizumab
- Drug: placebo

Other Study ID Numbers

- ACD4412n

Study Start (Actual)

2008 02

Primary Completion (Actual)

2009 01

Study Completion (Actual)

2009 01

Enrollment (Actual)

89

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)

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:

- Provide written informed consent and Health Insurance Portability and Accountability Act of 1996 (HIPAA) documents
- Be aged 18 years or older
- Have chronic (6 months or greater) moderate to severe plaque psoriasis with involvement of the scalp
- Have a whole body Physicians Global Assessment (PGA) rating of moderate (3) or severe (4) for psoriasis
- Have a scalp surface area affected by plaque psoriasis of 30% or more, assessed using Psoriasis Scalp Severity Index (PSSI)
- Have at least one of three clinical signs involving the scalp (erythema, induration, and desquamation) be rated as at least moderate (2) with the other two rated as at least slight (1) using PSSI
- Be a candidate for systemic therapy in the opinion of the investigator
- Be naive to efalizumab treatment
- For women of childbearing potential, must be willing to use a method of contraception acceptable to the investigator to prevent pregnancy and agree to continue to practice an acceptable method of contraception for the duration of their participation in the study and for 6 weeks after the last dose of efalizumab

Exclusion Criteria:

- Have had previous exposure to efalizumab or a history of hypersensitivity to any of its components
- Are using any excluded therapy
- Have a history of drug or alcohol abuse in the past five years
- Have a history in the past 5 years of a serious infection or currently have an ongoing uncontrolled bacterial, viral, fungal, or atypical mycobacterial infection
- Have any history of opportunistic infections (e.g., systemic fungal infections, parasites)
- Are seropositive for hepatitis B antigen, hepatitis C antibody, or human immunodeficiency virus (HIV)
- Have a history of active tuberculosis or are currently undergoing treatment for tuberculosis, including latent tuberculosis with isoniazid
- Have the presence or history of malignancy within the past 5 years, including lymphoproliferative disorders
- Are pregnant or breastfeeding
- Have a diagnosis of hepatic cirrhosis, regardless of cause or severity
- Have a history in the last 5 years of thrombocytopenia
- Have a history in the last 5 years of hemolytic anemia or any other clinically significant anemia
- Have been exposed to any experimental and/or unapproved drugs or treatments within 30 days or 5 half lives, whichever is longer, before the screening visit

- Have been vaccinated with a live virus or live bacteria within the 14 days before the first dose of efalizumab
- Have any medical condition that, in the judgment of the investigator, would jeopardize the patients safety following exposure to study drug (efalizumab or placebo equivalent or would significantly interfere with the patient s ability to comply with the provisions of this protocol

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: Efalizumab	Drug: efalizumab • All patients received a conditioning dose of efalizumab 0.7 mg/kg subcutaneously (SC) on Day 0, followed by 11 weekly doses of 1.0 mg/kg SC beginning on Day 7. After 12 weeks of blinded treatment, all patients continued into the open-label treatment period from Day 84 (Week 12) through Day 168 (Week 24). • Other Names: ◦ Raptiva
Placebo Comparator: Placebo	Drug: placebo • All patients received a conditioning dose of placebo equivalent SC on Day 0, followed by 11 weekly doses of placebo SC beginning on Day 7. After 12 weeks of blinded treatment, all patients continued into the open-label efalizumab treatment period from Day 84 (Week 12) through Day 168 (Week 24).

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Proportion of Patients Who Achieved a ≥	Proportion of patients who achieved a ≥ 75% decrease in PSSI score at 12 weeks (Day 84) relative to baseline. The PSSI assessed: 1) extent	Week 12

75% Decrease in Psoriasis Scalp Severity Index (PSSI) Score at 12 Weeks	of scalp psoriasis (i.e., percentage of area involved), which was scored from 1 to 6, where 1 = <10% and 6 = 90-100%); and 2) clinical signs (erythema, induration, and desquamation), which were scored from 0 to 4, where 0 = Absent and 4 = Severest possible). The sum of the separate scores for erythema, induration, and desquamation was multiplied by the score for the involved area. The PSSI score range was therefore 0-72.	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Proportion of Patients Who Achieved a ≥ 75% Decrease in PSSI Score at 24 Weeks	Proportion of patients who achieved a ≥ 75% decrease in PSSI score at 24 weeks (Day 168) relative to baseline. The PSSI assessed: 1) extent of scalp psoriasis (i.e., percentage of area involved), which was scored from 1 to 6, where 1 = <10% and 6 = 90-100%); and 2) clinical signs (erythema, induration, and desquamation), which were scored from 0 to 4, where 0 = Absent and 4 = Severest possible). The sum of the separate scores for erythema, induration, and desquamation was multiplied by the score for the involved area. The PSSI score range was therefore 0-72.	Week 24
Proportion of Patients Who Achieved a ≥ 50% Decrease in PSSI Score at 12 Weeks	Proportion of patients who achieved a ≥ 50% decrease in PSSI score at 12 weeks (Day 84) relative to baseline. The PSSI assessed: 1) extent of scalp psoriasis (i.e., percentage of area involved), which was scored from 1 to 6, where 1 = <10% and 6 = 90-100%); and 2) clinical signs (erythema, induration, and desquamation), which were scored from 0 to 4, where 0 = Absent and 4 = Severest possible). The sum of the separate scores for erythema, induration, and desquamation was multiplied by the score for	Week 12

	the involved area. The PSSI score range was therefore 0-72.	
Proportion of Patients Who Achieved a ≥ 50% Decrease in PSSI Score at 24 Weeks	Proportion of patients who achieved a ≥ 50% decrease in PSSI score at 24 weeks (Day 168) relative to baseline. The PSSI assessed: 1) extent of scalp psoriasis (i.e., percentage of area involved), which was scored from 1 to 6, where 1 = <10% and 6 = 90-100%); and 2) clinical signs (erythema, induration, and desquamation), which were scored from 0 to 4, where 0 = Absent and 4 = Severest possible). The sum of the separate scores for erythema, induration, and desquamation was multiplied by the score for the involved area. The PSSI score range was therefore 0-72.	Week 24
Proportion of Patients Who Achieved a Whole Body (Including Scalp) Physicians Global Assessment (PGA) Rating of Clear (0), Almost Clear (1), or Mild (2) at 12 Weeks	Proportion of patients who achieved a whole body (including scalp) PGA rating of 0, 1, or 2 at 12 weeks (Day 84) Physicians Global Assessment (PGA) scale: 0: Clear. No signs of plaque psoriasis. 1. Almost clear. Just perceptible erythema and just perceptible scaling. 2. Mild disease. Light pink erythema with minimal scaling. 3. Moderate disease. Dull red, clearly distinguishable erythema with diffuse scaling, some thickening. 4. Severe disease. Deep/dark red erythema with clearly obvious and diffuse scaling and thickening.	Week 12
Proportion of Patients Who Achieved a Whole Body	Proportion of patients who achieved a whole body (including scalp) PGA rating of 0, 1, or 2 at 24 weeks (Day 168) For details on the PGA	Week 24

(Including Scalp) PGA Rating of Clear (0), Almost Clear (1), or Mild (2) at 24 Weeks	scale, refer to the Secondary Outcome Measure Description for 12 weeks.	
Mean Change in Scalpdex Score at 12 Weeks	Mean change in Scalpdex score at 12 weeks (Day 84) relative to baseline. The Scalpdex point scoring scale ranges from 1=NEVER, 2= RARELY , 3= SOMETIMES , 4= OFTEN and 5= ALL THE TIME .	The two time points for Mean Change in Scalpdex Score at 12 Weeks are Day 0 and Day 84
Mean Change in Scalpdex Score at 24 Weeks	Mean change in Scalpdex score at 24 weeks (Day 168) relative to baseline. The Scalpdex point scoring scale ranges from 1=NEVER, 2= RARELY , 3= SOMETIMES , 4= OFTEN and 5= ALL THE TIME .	Week 24
Mean Change in a Visual Analog Scale (VAS) of Scalp Itch at 12 Weeks	Mean change in VAS of patient-reported scalp itch at 12 weeks (Day 84) relative to baseline. The Visual Analog Scale (VAS) of patient-reported scalp itch measured the severity of a patient s scalp itch on a scale of 0 to 10, where 0 was "no itching," 5 was "moderate itching," and 10 was "severe itching."	Week 12

Mean Change in VAS of Patient-reported Scalp Itch at 24 Weeks	Mean change in VAS of patient-reported scalp itch at 24 weeks (Day 168) relative to baseline. The Visual Analog Scale (VAS) of patient-reported scalp itch measured the severity of a patient s scalp itch on a scale of 0 to 10, where 0 was "no itching," 5 was "moderate itching," and 10 was "severe itching."	Week 24
Mean Change in Percentage of Whole Body (Including Scalp) Body Surface Area (BSA) Affected by Psoriasis at 12 Weeks	Mean change in percentage of whole body (including scalp) BSA affected by psoriasis at 12 weeks (Day 84) relative to baseline. BSA was assessed by percentage of sites affected per body segment (head, trunk, and limbs). Investigators were instructed to use the "rule of palm" to estimate lesional skin BSA (1% BSA = palm to first interphalangeal joint).	Week 12
Mean Change in Percentage of Whole Body (Including Scalp) BSA Affected by Psoriasis at 24 Weeks	Mean change in percentage of whole body (including scalp) BSA affected by psoriasis at 24 weeks (Day 168) relative to baseline. BSA was assessed by percentage of sites affected per body segment (head, trunk, and limbs). Investigators were instructed to use the "rule of palm" to estimate lesional skin BSA (1% BSA = palm to first interphalangeal joint).	Week 24

Collaborators and Investigators

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

Sponsor

Genentech, Inc.

Collaborators

No information provided

Investigators

- Study Director: Ivor Caro, M.D., Genentech, 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
2008-04-28

First Submitted that Met QC Criteria
2008-04-28

First Posted (Estimated)
2008-04-30

Results Reporting Dates

Results First Submitted
2010-08-24

Results First Submitted that Met QC Criteria
2011-01-18

Results First Posted (Estimated)
2011-02-14

Study Record Updates

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

Last Update Posted
2017-06-06

Last Verified
2017-05

More Information

Terms related to this study

Keywords Provided by Genentech, Inc.

Raptiva
Moderate plaque psoriasis
Severe plaque psoriasis
Scalp

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

Adalimumab in Adult Japanese Subjects With Psoriasis

ClinicalTrials.gov ID **NCT00647400**

Sponsor Abbott

Information provided by Abbott

Last Update Posted 2011 04 08

Study Details Tab

Study Overview

Brief Summary

To evaluate efficacy, safety, and pharmacokinetics of adalimumab in Japanese participants with psoriasis

Detailed Description

This was a continuation trial of adalimumab in participants with moderate to severe chronic plaque psoriasis who had completed Study M04 688 (NCT00338754), a 24 week, double blind, placebo controlled study. This study was an open label extension study that continued until the approval of adalimumab for the treatment of psoriasis in Japan.

During Study M04 688 (NCT00338754), participants received 24 weeks of treatment with adalimumab 40 mg every other week (eow) with or without a loading dose, adalimumab 80 mg eow, or placebo.

At the start of this study, participants who had received adalimumab 40 mg eow or adalimumab 80 mg eow in Study M04 688 (NCT00338754) continued on the same treatment regimen. Participants who had received placebo during Study M04 688 (NCT00338754) were re randomized at the start of this study to receive adalimumab 40 mg eow or adalimumab 80 mg eow.

Participants in the adalimumab 40 mg eow treatment group who failed to achieve a PASI50 response (>= 50% reduction in the Psoriasis Area and Severity Index score from Baseline of Study M04 688 [NCT00338754]) at or anytime after Week 12 of this study were given the option to increase their dose to adalimumab 80 mg eow. Once the dose was escalated, there was no option to de escalate dosing back to 40 mg eow. Participants who failed to achieve PASI50 responses while receiving adalimumab 80 mg eow may have been discontinued from the study after evaluating the risk/benefit of further treatment with adalimumab.

At Week 28 of this study, it was mandatory for all participants who started the study in the adalimumab 80 mg eow treatment group (i.e., not including the dose escalators described above) to reduce their dose to adalimumab 40 mg eow, regardless of their response status. Following this mandatory dose reduction, if these participants failed to achieve or maintain PASI50 response, they were permitted to escalate their dose to adalimumab 80 mg eow. There was no option to de escalate dosing back to 40 mg eow following dose escalation.

Data in this clinical trial results disclosure are analyzed as observed according to treatment received at the start of this study (i.e., adalimumab 40 mg eow or adalimumab 80 mg eow) regardless of subsequent dose escalation. Data are summarized according to participants cumulative exposure to adalimumab in Study M04 688 (NCT00338754) and this study.

Official Title

A Multicenter Open Label Continuation Study of the Long term Safety and Efficacy of Adalimumab (D2E7) in Japanese Subjects With Moderate to Severe Chronic Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Biological: adalimumab
- Biological: adalimumab

Other Study ID Numbers

- M04 702

Study Start

2006 04

Primary Completion (Actual)

2007 09

Study Completion (Actual)

2010 04

Enrollment (Actual)

147

Study Type

Interventional

Phase

Phase 2
Phase 3

Resource links provided by the National Library of Medicine

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

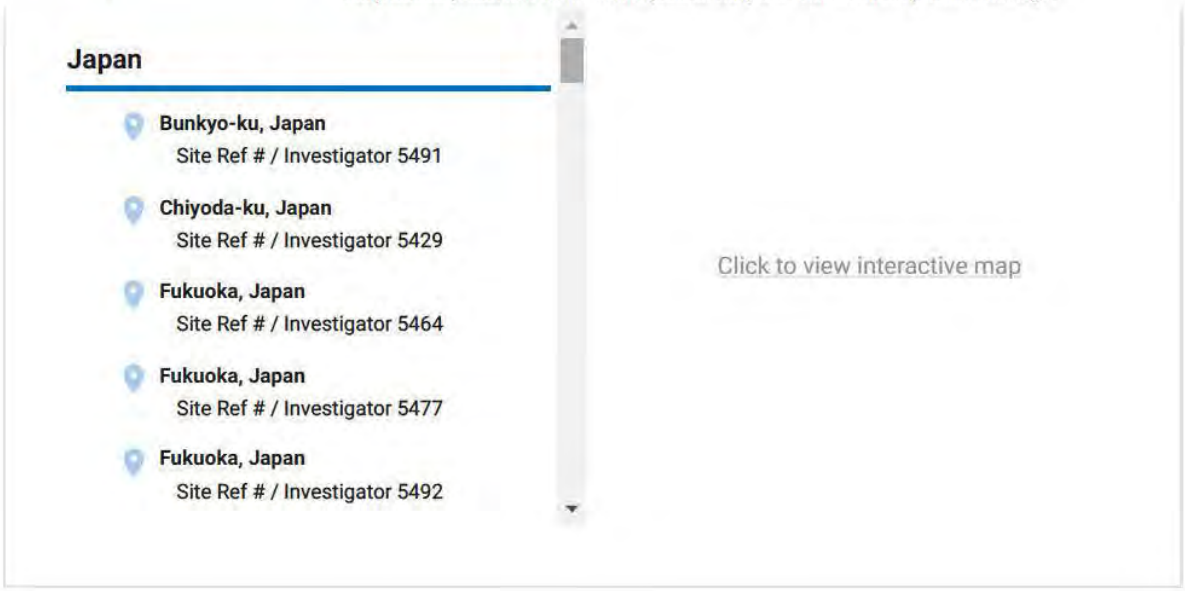
Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic graft versus host disease)

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.



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 who completed Study M04 688 (NCT00338754)

Exclusion Criteria:

Participant is considered by the investigator, for any reason, to be an unsuitable candidate for the study

Ages Eligible for Study

20 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: Adalimumab 40 mg every other week	Biological: adalimumab • Adalimumab 40 mg every other week, subcutaneous • Other Names: ◦ ABT-D2E7 ◦ Humira
Experimental: Adalimumab 80 mg every other week	Biological: adalimumab • Adalimumab 80 mg every other week, subcutaneous • Other Names: ◦ ABT-D2E7 ◦ Humira

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With a 50% Reduction in PASI (Psoriasis Area and Severity Index) Score Compared With Baseline PASI Score (PASI50 Response)	PASI scores range from 0 (best outcome) to 72 (worst outcome including erythema, induration, desquamation, and area affected). Baseline is defined as the last available PASI value prior to the first dose of study drug (adalimumab or placebo) in Study M04-688 (NCT00338754).	Baseline and 12, 24, 36, 52, 76, 100, 160, and 208 weeks after the first dose of adalimumab

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With a 75% Reduction in PASI (Psoriasis Area and Severity Index) Score Compared With Baseline PASI Score (PASI75 Response)	PASI scores range from 0 (best outcome) to 72 (worst outcome including erythema, induration, desquamation, and area affected). Baseline is defined as the last available PASI value prior to the first dose of study drug (adalimumab or placebo) in Study M04-688 (NCT00338754).	Baseline and 12, 24, 36, 52, 76, 100, 160, and 208 weeks after the first dose of adalimumab
Number of Participants With a 90% Reduction in PASI (Psoriasis	PASI scores range from 0 (best outcome) to 72 (worst outcome including erythema, induration, desquamation, and area affected). Baseline is defined as the last available PASI value prior to the first dose of study drug	Baseline and 12, 24, 36, 52, 76, 100, 160, and 208

Area and Severity Index) Score Compared With Baseline PASI Score (PASI90 Response)	(adalimumab or placebo) in Study M04-688 (NCT00338754).	weeks after the first dose of adalimumab

Collaborators and Investigators

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

Sponsor

Abbott

Collaborators

- Abbott Japan Co.,Ltd
- Eisai Co., Ltd.

Investigators

- Study Director: Kazuko Kobayashi, Abbott

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
2008-03-27

First Submitted that Met QC Criteria
2008-03-27

First Posted (Estimated)
2008-03-31

Results Reporting Dates

Results First Submitted
2009-12-04

Results First Submitted that Met QC Criteria
2009-12-04

Results First Posted (Estimated)
2010-01-11

Study Record Updates

Last Update Submitted that met QC Criteria
2011-04-01

Last Update Posted (Estimated)
2011-04-08

Last Verified
2011-04

More Information

Terms related to this study

Keywords Provided by Abbott

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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Record 1 of 1

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COMPLETED

A Study of the Safety and Efficacy of Ustekinumab (CNTO 1275) in Patients With Moderate to Severe Psoriasis

ClinicalTrials.gov ID **NCT00307437**

Sponsor Centocor Research & Development, Inc.

Information provided by Centocor Research & Development, Inc. (Responsible Party)

Last Update Posted 2013 01 24

Study Details Tab

Study Overview

Brief Summary

The primary objective of this study is to evaluate the efficacy and safety of ustekinumab (CNTO 1275) in the treatment of patients with moderate to severe plaque psoriasis.

Feedback

Detailed Description

Although numerous therapeutic options exist for the treatment of psoriasis, there is still a significant unmet medical need due to the limited effectiveness and/or significant side effect profile of current treatment options. Preclinical studies and early phase clinical studies suggest that interleukins 12 and 23, two molecules that are part of the communication network in the immune system, may play an important role in psoriasis. Ustekinumab (CNTO 1275) is a monoclonal antibody directed against interleukins 12 and 23. This is a randomized (study drug assigned by chance like flipping a coin), double blind (neither physician nor patient knows the name of the assigned drug), parallel group, multicenter study to determine the effectiveness and safety of two different doses of ustekinumab (CNTO 1275) administered subcutaneously (under the skin) as compared with placebo in patients with moderate to severe plaque type psoriasis (the most common type of psoriasis). The hypothesis is that ustekinumab (CNTO 1275) will be more effective in treatment of psoriasis than placebo, that the improvement in psoriasis will result in an improved quality of life for treated patients and that ustekinumab (CNTO 1275) will be generally well tolerated. Patients will receive ustekinumab (CNTO 1275), 45 or 90 mg, or placebo administered subcutaneously at weeks 0 and 4 weeks then every 12 weeks thereafter until week 52. For patients who partially respond to the starting regimen, the dosing interval may be adjusted to every 8 weeks. Patients will enter long term extension portion of the study at week 52 during which patients will continue to receive treatment with ustekinumab (CNTO 1275) and will be followed for a total of up to 264 weeks from the initial (week 0) administration of study agent.

The dose of ustekinumab (CNTO 1275) will be 45 or 90 mg or placebo administered subcutaneously at weeks 0 and 4 weeks then every 12 weeks thereafter. For patients who partially respond to the starting regimen, the dosing interval may be adjusted to every 8 weeks.

Official Title

A Phase 3, Multicenter, Randomized, Double blind, Placebo controlled Trial Evaluating the Efficacy and Safety of CNTO 1275 in the Treatment of Subjects With Moderate to Severe Plaque type Psoriasis.

Conditions

Psoriasis

Intervention / Treatment

- Drug: Placebo; Ustekinumab (CNTO 1275) 45 or 90 mg
- Drug: Ustekinumab (CNTO 1275) 45 mg
- Drug: Ustekinumab (CNTO 1275) 90 mg

Other Study ID Numbers

- CR006325
- C0743T09 (Other Identifier) (OTHER: Centocor R&D, USA)
- 2005 003530 17 (EudraCT Number)

Study Start

2005 05

Primary Completion (Actual)

2006 12

Study Completion (Actual)

2011 10

Enrollment (Actual)

1230

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.

United States

Alabama Locations

Birmingham, Alabama, United States

Click to view interactive map

Arkansas Locations

Little Rock, Arkansas, United States

California Locations

La Jolla, California, United States

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:

- Plaque type psoriasis diagnosed >= 6 months prior
- Plaque type psoriasis covering at least 10% of total body surface areas
- Psoriasis area and severity index score of >=12 at screening and baseline
- 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 throughout the trials and for 12 months following the last injection of study agent
- Have no history of latent or active tuberculosis (TB)

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 used any therapeutic agent targeted at reducing IL 12 or IL 23
- Patients who have had a Bacillus Calmette Guerin (BCG) vaccination within the previous 12 months prior to screening
- 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 prior to screening
- Patients who have or ever have had a nontuberculous mycobacterial infection or opportunistic infection
- Patients known to be infected with human immunodeficiency virus (HIV), 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
- Patients with a malignancy or who have a history of malignancy (with the exception of certain skin cancers and pre invasive cervical cancer)
- Patients participating in another trial using an investigational agent or procedure
- Systemic immunosuppressants within 4 weeks of the first administration of study agent

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, Care Provider, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Placebo Comparator: Group I: Placebo	Drug: Placebo; Ustekinumab (CNTO 1275) 45 or 90 mg • Placebo at Weeks 0 and 4 and blinded SC injections of ustekinumab, 45 or 90 mg, at Weeks 12 and 16; followed by a dosing regimen to be determined by patient s response status for Weeks 28 to 52; followed by unblinded dosing that may be adjusted at the investigator s discretion for Weeks 52 to 264
Experimental: Group II: Ustekinumab 45 mg	Drug: Ustekinumab (CNTO 1275) 45 mg • Ustekinumab, 45 mg, at Weeks 0 and 4 and every 12 weeks for Weeks 16 to 28. Followed by a dosing regimen to be determined by patient s response status for Weeks 28 to 52; followed by unblinded dosing that may be adjusted at the investigator s discretion for Weeks 52 to 264
Experimental: Group III: Ustekinumab 90 mg	Drug: Ustekinumab (CNTO 1275) 90 mg • Ustekinumab, 90 mg, at Weeks 0 and 4 and every 12 weeks for Weeks 16 to 28. Followed by a dosing regimen to be determined by patient s response status for Weeks 28 to 52; followed by unblinded dosing that may be adjusted at the investigator s discretion for Weeks 52 to 264

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With Psoriasis Area and Severity Index (PASI) Score of 75 Percent or Above at Week 12	Number of participants achieving greater than or equal to 75 percent improvement in PASI at Week 12. PASI is a widely used tool for the measurement of severity of psoriasis. This is a test of how bad a person s psoriasis is. The scale combines redness, scaling, and thickness, as well as overall body involvement to determine the PASI score. The scale ranges from 0 (best) to 72 (worst).	Week 0 to Week 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With Physician Global Assessment (PGA) of Cleared or Minimal at Week 12	Number of participants achieving a physician global assessment (PGA) (0 [none] to 5 [severe]) of cleared or minimal at Week 12. The PGA is 7-point scale used in clinical trials of various diseases. In this the physician checks the state of the disease and gives them score from 0 (clear) to 5 (severe).	Week 12
Change in Dermatology Life Quality Index (DLQI) at Week 12	Change in Dermatology Life Quality Index (DLQI) from baseline at Week 12. The DLQI is a 10-item questionnaire, that in addition to evaluating overall quality of life, can be used to assess 6 different aspects that may affect quality of life: symptoms and feelings, daily activities, leisure, work or school performance, personal relationships, and treatment. Scores range from	Baseline to Week 12

	0 (no impairment in quality of life) to 30 (most impairment in quality of life).	
Number of Participants Visits With Psoriasis Area and Severity Index (PASI) 75 From Week 40 Through Week 52	Number of visits at which participants randomized at Week 28 achieved at least 75 percent improvement from baseline in PASI from Week 40 through Week 52 in participants randomized at Week 28. PASI is a widely used tool for the measurement of severity of psoriasis. This is a test of how bad a persons psoriasis is. The scale combines redness, scaling, and thickness, as well as overall body involvement to determine the PASI score. The scale ranges from 0 (best) to 72 (worst).	Week 40 to Week 52

Collaborators and Investigators

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

Sponsor

Centocor Research & Development, 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
2006-03-24

First Submitted that Met QC Criteria
2006-03-24

First Posted (Estimated)
2006-03-28

Results Reporting Dates

Results First Submitted
2009-10-23

Results First Submitted that Met QC Criteria
2012-10-05

Results First Posted (Estimated)
2012-11-02

Study Record Updates

Last Update Submitted that met QC Criteria
2013-01-16

Last Update Posted (Estimated)
2013-01-24

Last Verified
2013-01

More Information

Terms related to this study

Keywords Provided by Centocor Research & Development, Inc.

Moderate to Severe Plaque Type Psoriasis
interleukin 23
IL 12
interleukin 12
interleukin 23
CNTO1275
biologic
Psoriasis
CNTO 1275
IL23
interleukin 12
IL 23
IL12
ustekinumab

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Dermatologic Agents
Ustekinumab

Study Documents

No study documents available

Record 1 of 1

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COMPLETED

Open-label Study of Subcutaneous Secukinumab to Evaluate Efficacy and Safety in Patients With Plaque Psoriasis Who Had Inadequate Response to Cyclosporine A

ClinicalTrials.gov ID NCT02547714

Sponsor Novartis Pharmaceuticals

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

Last Update Posted 2017 09 11

Study Details Tab

Study Overview

Brief Summary

Feedback

The purpose of this study was to assess the efficacy and safety of secukinumab at Week 16 based on psoriasis area and severity index (PASI) 75 in subjects who had inadequate response to cyclosporine A.

Official Title

A Multi center, Open label Study of Subcutaneous Secukinumab to Evaluate Efficacy and Safety for 16 Weeks in Patients With Plaque Psoriasis Who Had Inadequate Response to Cyclosporine A

Conditions

Plaque Psoriasis

Intervention / Treatment

- Drug: Secukinumab (AIN457)

Other Study ID Numbers

- CAIN457AJP01

Study Start (Actual)

2015 06 16

Primary Completion (Actual)

2016 05 02

Study Completion (Actual)

2016 05 02

Enrollment (Actual)

34

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) 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.

Japan

Aichi Locations

Nagoya city, Aichi, Japan, 467-8602
Novartis Investigative Site

Fukuoka Locations

Fukuoka-city, Fukuoka, Japan, 814-0180
Novartis Investigative Site

Kanagawa 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:

- Plaque psoriasis diagnosed for at least 6 months before baseline Treated with cyclosporine A for at least 12 weeks prior to baseline
- Currently treated with cyclosporine A at baseline for psoriasis but is a primary or secondary inadequate response as defined at baseline by:
    - PASI score of 10 or greater and
    - IGA mod 2011 score of 2 or greater (based on a scale of 0 to 4)

Exclusion Criteria:

- Forms of psoriasis other than plaque (e.g., pustular, erythrodermic and guttate psoriasis). Drug induced psoriasis (i.e., new onset or current exacerbation from beta blockers, calcium channel blockers or lithium).
- Patients who have to discontinue cyclosporine A treatment due to side effects like renal impairment (serum creatinine exceeding 176.8 µmol/L [2.0 mg/dL]) and hypertension at screening.

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 : Non Randomized
Interventional Model : Single Group Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Secukinumab (AIN457) 300 mg Participants received secukinumab 300 mg subcutaneously (s.c.) (two 150 mg injections) on Day 1 and at Weeks 1, 2, 3, 4, 8 and 12.	Drug: Secukinumab (AIN457) • Secukinumab was supplied as 150 mg doses, provided in 1 mL prefilled syringes.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Who Achieved ≥ 75% Psoriasis Area and Severity Index (PASI 75)	PASI is a combined assessment of a lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). The body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for a 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	Week 16

	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 75 was defined as participants achieving >= 75% improvement from baseline.	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Mean Percent Change From Baseline in PASI Score	PASI is a combined assessment of a lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). The body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for a 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 change from baseline indicates improvement.	Week 4
Percentage of Participants Achieving PASI 50 or PASI 75	PASI is a combined assessment of a lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). The body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for a 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 4

	PASI 50 and PASI 75 were defined as participants achieving >= 50% or >= 75% improvement from baseline, respectively.	
Percentage of Participants Achieving PASI 90 and Investigator s Global Assessment (IGA) of 0 or 1 Response	PASI is a combined assessment of a lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). The body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for a 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 was defined as participants achieving >= 90% improvement from baseline. The IGA scale is static, i.e. it referred exclusively to the participant s disease at the time of 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 and 4 = severe.	Week 16
Mean Percent Change From Baseline in Dermatology Life Quality Index (DLQI) Score	The DLQI is a ten item general dermatology disability index designed to assess health-related quality of life in adult participants with skin diseases such as eczema, psoriasis, acne and viral warts. It is a self-administered questionnaire which includes domains of daily activity, leisure, personal relationships, symptoms and feelings, treatment and school/work activities. Each domain has 4 response categories ranging from 0 (not at all) to 3 (very much). "Not relevant" is a valid score also and is scored as 0. The DLQI	Week 16

	total score is a sum of all 10 responses. Scores range from 0 to 30 with higher scores indicating greater health-related quality of life impairment. A negative mean percentage change from baseline indicates improvement.	
Percentage of Participants Achieving DLQI 0 or 1	The DLQI is a ten item general dermatology disability index designed to assess health-related quality of life in adult participants with skin diseases such as eczema, psoriasis, acne and viral warts. It is a self-administered questionnaire which includes domains of daily activity, leisure, personal relationships, symptoms and feelings, treatment and school/work activities. Each domain has 4 response categories ranging from 0 (not at all) to 3 (very much). "Not relevant" is a valid score also and is scored as 0. The DLQI total score is a sum of all 10 responses. Scores range from 0 to 30 with higher scores indicating greater health-related quality of life impairment.	Week 16

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

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Study Registration Dates

First Submitted
2015-07-12

First Submitted that Met QC Criteria
2015-09-10

First Posted (Estimated)
2015-09-11

Results Reporting Dates

Results First Submitted
2017-04-11

Results First Submitted that Met QC Criteria
2017-04-11

Results First Posted
2017-06-27

Study Record Updates

Last Update Submitted that met QC Criteria
2017-08-10

Last Update Posted
2017-09-11

Last Verified
2017-08

More Information

Terms related to this study

Keywords Provided by Novartis (Novartis Pharmaceuticals)

cyclosporine A

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

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Record 1 of 1

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COMPLETED

A Comparison of 000-0551 Lotion Versus Vehicle Lotion in Subjects With Plaque Psoriasis (Study -305)

ClinicalTrials.gov ID NCT01882647

Sponsor Therapeutics, Inc.

Information provided by Therapeutics, Inc. (Responsible Party)

Last Update Posted 2017 02 13

Study Details Tab

Study Overview

Brief Summary

This Phase 3 study has been designed to determine and compare the efficacy and safety of 000 0551 Lotion and Vehicle Lotion applied twice daily for two weeks in subjects with plaque psoriasis.

Feedback

Official Title

A Multicenter, Randomized, Double Blind, Parallel Group Comparison of 000 0551 Lotion Versus Vehicle Lotion in Subjects With Plaque Psoriasis (Study 305)

Conditions

Plaque Psoriasis

Intervention / Treatment

- Drug: 000 0551 Lotion
- Drug: Vehicle Lotion

Other Study ID Numbers

- 000 0551 305

Study Start

2013 06

Primary Completion (Actual)

2014 03

Study Completion (Actual)

2014 03

Enrollment (Actual)

222

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)

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 and Beauty Dermatology Center, PC

Florida Locations

Brandon, Florida, United States
MOORE Clinical Research, Inc.

Miami, Florida, United States

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:

- Subject has a clinical diagnosis of stable plaque psoriasis involving a minimum of 2% and no more than 12% affected body surface area.
- Subject has an Investigator s Global Assessment (IGA) score of at least three (moderate) at study start.
- If subject is a woman of childbearing potential, she must have a negative urine pregnancy test and agree to use an effective form of birth control for the duration of the study

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 (including laser), photo chemotherapy or other forms of photo based therapy for the treatment of their psoriasis within 30 days prior to study start.
- Subject has used any systemic methotrexate, retinoids, systemic corticosteroids [including intralesional, intra articular, and intramuscular corticosteroids], cyclosporine or analogous products within 90 days prior to study start.
- Subject has used any systemic biologic therapy (i.e., FDA approved or experimental therapy) within five 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 or is intending to have such exposure during the study.
- Subject has used topical body (excluding the scalp) psoriasis therapy (including coal tar, anthralin, steroids, retinoids, vitamin D analogs) 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., propanolol) or angiotensin converting enzyme (ACE) 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: Active Arm Topical lotion, applied twice daily	Drug: 000-0551 Lotion
Placebo Comparator: Vehicle Arm Topical lotion, applied twice daily	Drug: Vehicle Lotion

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Percentage of Subjects Rated a "Treatment Success" Based on the Investigator s Global Assessment (IGA)	The IGA score is a static evaluation of the overall or "average" degree of severity of a subject s disease, taking into account all of the subject s psoriatic lesions. "Treatment success" is defined as a score of 0 or 1 representing "cleared" or "almost cleared" at Day 15 with at least a two grade decrease in severity score relative to Baseline. IGA is measured on a 5-point scale, ranging from 0 (clear) to 4 (severe/very severe).	Day 15

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Percentage of Subjects Rated a "Treatment Success" for Each of the Clinical Signs of Psoriasis (Scaling, Erythema and Plaque Elevation)	A static assessment of the overall or "average" degree of severity of each of three key characteristics present within all of the subject s psoriatic lesions. "Treatment success" is defined as a score of 0 or 1 representing "cleared" or "almost cleared" at Day 15 with at least a two grade decrease in severity score relative to Baseline. Each clinical sign of psoriasis is measured on a 5-point scale, ranging from 0 (clear) to 4 (severe/very severe).	Day 15

Other Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Subjects With	Interim analysis of IGA. "Treatment success" and IGA as defined in the primary outcome measure.	Day 8

IGA "Treatment Success" at Day 8		
Percentage of Subjects Rated a "Treatment Success" for Each of the Clinical Signs of Psoriasis (Scaling, Erythema and Plaque Elevation) at Day 8	Interim analysis of clinical signs of psoriasis. "Treatment success" for each of the clinical signs of psoriasis (scaling, erythema and plaque elevation) at Day 8 as defined in the secondary outcome measure.	Day 8
Change From Baseline in Pruritus Score at Day 15	Pruritus scale will be used to assess the subjective and multidimensional experience of the subject s pruritus (itching) during the previous two weeks at Baseline and Day 15. Possible scores range from 5 (no pruritus) to 25 (most severe pruritus).	Baseline and Day 15
Change in Percent Body Surface Area (% BSA) With Active Psoriasis at Day 15	The investigator will use the assumption that 1% BSA is approximately equal to the surface area of the subject s palm and fingers, with the fingers extended yet grouped together, creating a flat oval-like surface area.	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, Ph.D., 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

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Study Registration Dates

First Submitted
2013-06-18

First Submitted that Met QC Criteria
2013-06-18

First Posted (Estimated)
2013-06-20

Results Reporting Dates

Results First Submitted
2016-03-10

Results First Submitted that Met QC Criteria

2016-12-20

Results First Posted

2017-02-13

Study Record Updates

Last Update Submitted that met QC Criteria

2016-12-20

Last Update Posted

2017-02-13

Last Verified

2016-12

More Information

Terms related to this study

Keywords Provided by Therapeutics, Inc.

psoriasis
lotion
investigator s global assessment

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

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Record 1 of 1

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COMPLETED

Effects of Etanercept on Nail Psoriasis and Plaque Psoriasis

ClinicalTrials.gov ID **NCT00581100**

Sponsor Wyeth is now a wholly owned subsidiary of Pfizer

Information provided by Wyeth is now a wholly owned subsidiary of Pfizer (Responsible Party)

Last Update Posted 2013 02 25

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to evaluate if Etanercept administered at a higher initial dose provides greater improvement in nail and skin psoriasis symptoms than a regimen with a lower initial dose.

Detailed Description

Feedback

This study will assess the effects of the 2 Etanercept regimens on fingernail psoriasis over 24 weeks among patients with both skin and fingernail symptoms who have previously failed at least one therapy for nail psoriasis. The endpoint of 24 weeks was chosen to allow sufficient time for normal nail growth.

Official Title

Randomised, Open label Preliminary Study to Assess the Effects of 2 Regimens of Etanercept on Nail and Skin Symptoms in Patients With Nail Psoriasis and Plaque Psoriasis

Conditions

Nail Psoriasis | Plaque Psoriasis

Intervention / Treatment

- Drug: etanercept

Other Study ID Numbers

- 0881A6 409

Study Start

2007 09

Primary Completion (Actual)

2009 08

Study Completion (Actual)

2009 10

Enrollment (Actual)

136

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)

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:

- 18 years of age or older
- Active, stable plaque psoriasis defined by the following criteria:
  - Body surface area (BSA) ≥ 10 % at screening and baseline
  - Or, PASI >10 at screening and baseline
  - Or, PGA of Psoriasis status of moderate or worse (moderate, marked, or severe) at screening and baseline
  - Or, DLQI > 10 at baseline
- Active fingernail psoriasis defined as target fingernail NAPSI ≥ 2 and overall NAPSI > 14 Target nail is defined as the nail with the highest nail score (matrix+bed scores) at baseline. Should more than one fingernail have the same score, the target fingernail will be chosen by the investigator.
- Failure of at least one systemic psoriasis therapy for nail psoriasis
- Eligible to receive biologic therapy for psoriasis in accordance to local guidelines

Exclusion Criteria:

- Evidence of Skin conditions other than psoriasis
- Psoralen plus ultraviolet radiation (PUVA), cyclosporine, alefacept, methotrexate, acitretin, or any other systemic anti psoriasis therapy within 28 days of study drug initiation
- Prior exposure to any TNF inhibitor. Prior exposure to efalizumab

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: 1 etanercept 50 mg SC injection twice weekly for 12 weeks reducing to etanercept 50 mg once weekly to week 24	Drug: etanercept • Subjects randomized to Arm 1 shall be treated with ETN 50 mg twice weekly for 12 weeks reducing thereafter to ETN 50 mg once weekly to 24 weeks. Subjects randomized to Arm 2 shall be treated with ETN 50 mg once weekly for the entire 24 week treatment period.
Active Comparator: 2 etanercept 50 mg SC once weekly for the complete 24 week treatment period	Drug: etanercept • Subjects randomized to Arm 1 shall be treated with ETN 50 mg twice weekly for 12 weeks reducing thereafter to ETN 50 mg once weekly to 24 weeks. Subjects randomized to Arm 2 shall be treated with ETN 50 mg once weekly for the entire 24 week treatment period.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Baseline in Nail Psoriasis Severity Index (NAPSI) Score for Target Fingernail	Target fingernail (highest matrix + bed scores at baseline) divided with imaginary lines into quadrants and graded for nail matrix and nail bed psoriasis. Sum of scores = total score for that nail (0-8). Nail Matrix Psoriasis = pitting, leukonychia, red spots in lunula, and/or nail plate crumbling. Nail Bed Psoriasis = onycholysis, splinter hemorrhages, oil drop (salmon patch) discoloration, and/or nail bed hyperkeratosis. Range for both scores: 0 (none), 1 (present in 1/4 nail), 2 (present in 2/4 nail), 3 (present in 3/4 nail), 4 (present in 4/4 nail). Higher scores = more severe psoriasis.	Baseline, Week 24

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Baseline in Overall Nail Psoriasis Severity Index (NAPSI) Score	NAPSI (matrix + bed score) performed on dorsal views of 8 fingers, excluding thumb; range: 0 to 8. Overall NAPSI score = sum of all fingernail scores; range: 0 to 64. Nails were divided into quadrants and graded for nail matrix and bed psoriasis. Nail Matrix Psoriasis = pitting, leukonychia, red spots in lunula, and/or nail plate crumbling. Nail Bed Psoriasis = onycholysis, splinter hemorrhages, oil drop (salmon patch) discoloration, and/or nail bed hyperkeratosis. Range for both scores: 0 (none), 1 (present 1/4 nail), 2 (present 2/4 nail), 3 (present 3/4 nail), and 4 (present 4/4 nail).	Baseline, Week 24

Percent of Participants Who Achieved a 50% Improvement in the Nail Psoriasis Severity Index (NAPSI) Score for Target Fingernail at Week 12 and Week 24	Target fingernail (highest matrix + bed scores at baseline) divided with imaginary lines into quadrants and graded for nail matrix and nail bed psoriasis. Sum of scores = total score for that nail (0-8). Nail Matrix Psoriasis = pitting, leukonychia, red spots in lunula, and/or nail plate crumbling. Nail Bed Psoriasis = onycholysis, splinter hemorrhages, oil drop (salmon patch) discoloration, and/or nail bed hyperkeratosis. Range for both scores 0-8: 0 (none), 1 (present in 1/4 nail), 2 (present in 2/4 nail), 3 (present in 3/4 nail),4 (present in 4/4 nail). Higher score = more severe psoriasis.	Week 12, Week 24
Percent of Participants Who Achieved a 75% Improvement in the Nail Psoriasis Severity Index (NAPSI) Score for Target Fingernail at Week 12 and Week 24	Target fingernail (highest matrix + bed scores at baseline) divided with imaginary lines into quadrants and graded for nail matrix and nail bed psoriasis. Sum of scores = total score for that nail (0-8). Nail Matrix Psoriasis = pitting, leukonychia, red spots in lunula, and/or nail plate crumbling. Nail Bed Psoriasis = onycholysis, splinter hemorrhages, oil drop (salmon patch) discoloration, and/or nail bed hyperkeratosis. Range for both scores: 0 (none), 1 (present in 1/4 nail), 2 (present in 2/4 nail), 3 (present in 3/4 nail), 4 (present in 4/4 nail). Higher scores = more severe psoriasis.	Week 12, Week 24
Percent of Participants Who Achieved a 50% Improvement in the Nail Psoriasis Severity Index (NAPSI) for Overall NAPSI	NAPSI (matrix + bed score) performed on dorsal views of 8 fingers, excluding thumb; range: 0 to 8. Overall NAPSI score = sum of all fingernail scores; range: 0 to 64. Nails were divided into quadrants and graded for nail matrix and bed psoriasis. Nail Matrix Psoriasis = pitting, leukonychia, red spots in lunula, and/or nail plate crumbling. Nail Bed Psoriasis = onycholysis, splinter hemorrhages, oil drop (salmon patch)	Week 12, Week 24

Score at Week 12 and Week 24	discoloration, and/or nail bed hyperkeratosis. Range for both scores: 0 (none), 1 (present 1/4 nail), 2 (present 2/4 nail), 3 (present 3/4 nail), and 4 (present 4/4 nail).	
Percent of Participants Who Achieved a 75% Improvement in the Nail Psoriasis Severity Index (NAPSI) for Overall NAPSI Score at Week 12 and Week 24	NAPSI (matrix + bed score) performed on dorsal views of 8 fingers, excluding thumb; range: 0 to 8. Overall NAPSI score = sum of all fingernail scores; range: 0 to 64. Nails were divided into quadrants and graded for nail matrix and bed psoriasis. Nail Matrix Psoriasis = pitting, leukonychia, red spots in lunula, and/or nail plate crumbling. Nail Bed Psoriasis = onycholysis, splinter hemorrhages, oil drop (salmon patch) discoloration, and/or nail bed hyperkeratosis. Range for both scores: 0 (none), 1 (present 1/4 nail), 2 (present 2/4 nail), 3 (present 3/4 nail), and 4 (present 4/4 nail).	Week 12, Week 24
Change From Baseline in the Psoriasis Area and Severity Index (PASI) Score	Combined assessment of lesion severity and area affected into single score; range: 0 (no disease) to 72 (maximal disease). Body was divided into 4 sections (head, arms, trunk, legs); each area was scored by itself and scores were 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 * area score * weight of section (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4).	Baseline, Week 24
Percent of Participants Achieving a 50% Improvement in	Combined assessment of lesion severity and area affected into single score; range: 0 (no disease) to 72 (maximal disease). Body was divided into 4 sections (head, arms, trunk, legs); each area was scored by itself and	Week 12 , Week 24

the Psoriasis Area and Severity Index (PASI) Score at Week 12 and Week 24	scores were 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 * area score * weight of section (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4).	
Percent of Participants Achieving a 75% Improvement in the Psoriasis Area and Severity Index (PASI) Score at Week 12 and Week 24	Combined assessment of lesion severity and area affected into single score; range: 0 (no disease) to 72 (maximal disease). Body was divided into 4 sections (head, arms, trunk, legs); each area was scored by itself and scores were 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 * area score * weight of section (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4).	Week 12 , Week 24
Change From Baseline in Physician Global Assessment (PGA) of Psoriasis	Physician Global Assessment (PGA) of Psoriasis: score based on dermatologist s assessment of disease averaged over all lesions of head, scalp, and neck. Overall lesions were graded for 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.	Baseline, Week 24
Percent of Participants Achieving a Status on the Physician	Physician Global Assessment (PGA) of Psoriasis: score based on dermatologist s assessment of disease averaged over all lesions of head, scalp, and neck. Overall lesions were graded for induration, erythema,	Baseline, Week 24 or Early Termination

Global Assessment (PGA) of Psoriasis of Clear or Almost Clear	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. Assessment of clear or almost clear = PGA score of 0 (no evidence), or 1 (minimal/faint).	
Percent of Participants Achieving a Status on the Physician Global Assessment (PGA) of Psoriasis of Mild or Better	Physician Global Assessment (PGA) of Psoriasis: score based on dermatologist s assessment of disease averaged over all lesions of head, scalp, and neck. Overall lesions were graded for 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. Assessment of mild or better = PGA score of ≤ 2 (mild plaque elevation, mild scaling, and light red coloration).	Baseline, Week 24 or Early Termination
Change From Baseline in the Dermatology Life Quality Index (DLQI)	Self-administered questionnaire to measure health-related quality of life (QoL)of adult patients suffering from skin disease; 10 questions concerning patients perception of impact of their disease over last week encompassing aspects such as symptoms, feelings, daily activities, leisure, work, school, personal relationships and side effects of treatment. Questions scored on a 4-point Likert scale: 0 (not at all/not relevant), 1 (a little), 2 (a lot), and 3 (very much). Scores of individual items (0-3) were added to yield a total score (0-30); higher score = greater impairment of patient s QoL.	Baseline, Week 24
Change From Baseline in Physician Assessment of Nail Psoriasis	Physician global assessment of disease activity using a visual analog scale; range: 0 (no nail disease) to 100 (worst possible nail disease).	Baseline, Week 24

Activity Visual Analog Scale (VAS)		
Change From Baseline in Patient Assessment of Nail Psoriasis Activity Visual Analog Scale (VAS)	Patient global assessment of disease activity using a visual analog scale; range: 0 (no nail disease) to 100 (worst possible nail disease).	Baseline, Week 24
Change From Baseline in Physician Fingernail Grading Assessment Total Score	Physician assessment of disease activity for each fingernail; range: 0 (no disease), 1 (mild disease, 2 (moderate disease), or 3 (severe disease). Total score range = 0-30.	Baseline, Week 24

Collaborators and Investigators

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

Sponsor

Wyeth is now a wholly owned subsidiary of 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

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
2007-12-21

First Submitted that Met QC Criteria
2007-12-21

First Posted (Estimated)
2007-12-27

Results Reporting Dates

Results First Submitted
2010-08-03

Results First Submitted that Met QC Criteria
2010-08-03

Results First Posted (Estimated)
2010-08-30

Study Record Updates

Last Update Submitted that met QC Criteria

2013-02-20

Last Update Posted (Estimated)

2013-02-25

Last Verified

2013-02

More Information

Terms related to this study

Keywords Provided by Wyeth is now a wholly owned subsidiary of Pfizer

Nail Psoriasis
Plaque 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

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

A Double Blind Study in Pediatric Subjects With Chronic Plaque Psoriasis, Studying Adalimumab vs. Methotrexate

ClinicalTrials.gov ID **NCT01251614**

Sponsor AbbVie (prior sponsor, Abbott)

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

Last Update Posted 2017 09 25

Study Details Tab

Study Overview

Brief Summary

This study will compare how well adalimumab works versus methotrexate (MTX) in children with moderate to severe psoriasis in the short term. It will also study how safe and how well adalimumab works in the long term and how long disease response can be maintained after stopping therapy.

Feedback

Detailed Description

The study had a 30 day screening period and a multi period study design, as described below:

Period A Primary Treatment Phase: Participants were randomized to receive adalimumab 0.8 mg/kg, adalimumab 0.4 mg/kg, or MTX in 1:1:1 ratio for 16 weeks.

Period B Treatment Withdrawal Phase: Responders were withdrawn from active treatment and monitored for loss of disease control for up to 36 weeks.

Period C Re Treatment Phase: Participants who had experienced loss of disease control in Period B were re treated with adalimumab for 16 weeks.

Period D Long Term Follow Up Phase: Participants received adalimumab or were observed off treatment (if disease remained under control) for 52 weeks.

Official Title

A Multicenter, Randomized, Double dummy, Double blind Study Evaluating Two Doses of Adalimumab Versus Methotrexate (MTX) in Pediatric Subjects With Chronic Plaque Psoriasis (Ps)

Conditions

Plaque Psoriasis

Intervention / Treatment

- Biological: Adalimumab
- Drug: Methotrexate
- Biological: Placebo to Adalimumab
- Drug: Placebo to Methotrexate

Other Study ID Numbers

- M04 717
- 2009 013072 52 (EudraCT Number)

Study Start

2010 12

Primary Completion (Actual)

2013 12

Study Completion (Actual)

2015 02

Enrollment (Actual)

114

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: Methotrexate (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Methotrexate) 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 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 is ≥ 4 years and < 18 years of age;
2. Subject weighs ≥ 13 kg;
3. Subject must have failed to respond to topical therapy;
4. Subject must need systemic treatment to control his/her disease and meet one of the following:
    - Physicians Global Assessment (PGA) ≥ 4
    - Body surface area (BSA) involved > 20%
    - Very thick lesions with BSA > 10%
    - Psoriasis Area and Severity Index (PASI) > 20
    - PASI > 10 and at least one of the following:
        - Active psoriatic arthritis unresponsive to non steroid anti inflammatory drugs (NSAIDs)
        - Clinically relevant facial involvement
        - Clinically relevant genital involvement
        - Clinically relevant hand and/or foot involvement
        - Childrens Dermatology Life Quality Index (CDLQI) > 10
5. If subject is < 12 years of age and resides in a geographic region where heliotherapy is practical, subject must have failed to respond, be intolerant, or have a contraindication to heliotherapy, or is not a suitable candidate for heliotherapy;
6. If ≥ 12 years of age, subject must have failed to respond, be intolerant, or have a contraindication to phototherapy, or is not a suitable candidate for phototherapy;
7. Subject must have a clinical diagnosis of psoriasis for at least 6 months as determined by the subject s medical history and confirmation of diagnosis through physical examination by the Investigator;
8. Subject must have stable plaque psoriasis for at least 2 months prior to Baseline

Exclusion Criteria:

1. Prior biologic use other than prior treatment with etanercept;
2. Treatment with etanercept therapy within 4 weeks prior to the Baseline visit; 3. Methotrexate (MTX) use within the past year or prior MTX use at any time where the subject did not respond, or did not tolerate MTX;

4. Contraindication for treatment with MTX during the study; 5. Erythrodermic psoriasis, generalized or localized pustular psoriasis, medication induced or medication exacerbated psoriasis or new onset guttate psoriasis; 6. Infection(s) requiring treatment with intravenous (IV) anti infectives within 30 days prior to the Baseline Visit or oral anti infectives within 14 days prior to the Baseline Visit; 7. Treatment of psoriasis with topical therapies such as corticosteroids, vitamin D analogs, or retinoids within 7 days prior to the Baseline visit; 8. Treatment of psoriasis with ultraviolet (UV)B phototherapy, excessive sun exposure, or the use of tanning beds within 7 days prior to the Baseline visit; 9. Treatment of psoriasis with

ultraviolet A with psoralen (PUVA) phototherapy, non biologic systemic therapies for the treatment of psoriasis, or systemic therapies known to improve psoriasis within 14 days prior to the Baseline visit.

Ages Eligible for Study

4 Years to 17 Years (Child)

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: Adalimumab 0.4 mg/kg In Period A participants received a single subcutaneous loading dose of adalimumab 0.4 mg/kg (up to a maximum of 20 mg) at Week 0 followed by every other week dosing beginning at Week 1. To maintain the blind, participants also received weekly dosing of methotrexate placebo tablets. Participants who were non-responders in Period A entered Period D directly and received open-label adalimumab at 0.8 mg/kg eow for up to 52 weeks. Participants who responded in Period A entered the Treatment Withdrawal Phase (Period B) for up to 36 weeks. Participants who experienced a loss of disease control in	Biological: Adalimumab • Adalimumab by subcutaneous injection every other week (eow) • Other Names: ◦ ABT-D2E7 ◦ Humira Drug: Placebo to Methotrexate • Orally once a week

Period B entered the Re-treatment Phase (Period C) and received blinded adalimumab 0.4 mg/kg eow for 16 weeks. Participants who completed Period B with no loss of disease control entered Period D and were observed off study medication for up to 52 weeks. Participants who completed Period C entered Period D for an additional 52 weeks of treatment with blinded adalimumab 0.4 mg/kg eow.	
Experimental: Adalimumab 0.8 mg/kg In Period A participants received a single subcutaneous loading dose of adalimumab 0.8 mg/kg (up to a maximum of 40 mg) at Week 0 followed by every other week dosing beginning at Week 1. To maintain the blind, participants also received weekly dosing of methotrexate placebo	Biological: Adalimumab • Adalimumab by subcutaneous injection every other week (eow) • Other Names: ◦ ABT-D2E7 ◦ Humira Drug: Placebo to Methotrexate • Orally once a week

tablets. Participants who were non-responders in Period A entered Period D directly and received open-label adalimumab at 0.8 mg/kg eow for up to 52 weeks. Participants who responded in Period A entered the Treatment Withdrawal Phase (Period B) for up to 36 weeks. Participants who experienced a loss of disease control in Period B entered the Re-treatment Phase (Period C) and received blinded adalimumab 0.8 mg/kg eow for 16 weeks. Participants who completed Period B with no loss of disease control entered Period D and were observed off study medication for up to 52 weeks. Participants who completed Period C entered Period D for an additional 52 weeks of treatment with blinded adalimumab 0.8 mg/kg eow.	
Active Comparator: Methotrexate	Drug: Methotrexate

Participants received 0.1 mg/kg methotrexate at Baseline (Week 0), and up to 0.4 mg/kg weekly (maximum dose of 25 mg/week) in Period A. Participants also received adalimumab placebo as a single subcutaneous loading dose at Week 0, followed by every other week (eow) dosing from Week 1. Participants who were non-responders in period A entered Period D directly and received open-label adalimumab at 0.8 mg/kg eow for up to 52 weeks. Participants who responded in Period A entered the Treatment Withdrawal Phase (Period B) for up to 36 weeks. Participants who experienced a loss of disease control in Period B entered the Re-treatment Phase (Period C) and received blinded adalimumab 0.8 mg/kg eow for 16 weeks. Participants who completed Period B with no loss of disease control	• Methotrexate 0.1 mg/kg at Week 0 and up to 0.4 mg/kg per week (maximum dose of 25 mg/week) orally. Biological: Placebo to Adalimumab • A single subcutaneous loading dose at Week 0 followed by eow dosing beginning at Week 1.	

entered Period D and were observed off study medication for up to 52 weeks. Participants who completed Period C entered Period D for an additional 52 weeks of treatment with blinded adalimumab 0.8 mg/kg eow.	

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Who Achieved a Psoriasis Area and Severity Index (PASI) 75 Response at Week 16	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 (no psoriasis) to 72 (very severe psoriasis). A PASI 75 response is defined as at least a 75% reduction (improvement) from Baseline in PASI score at Week 16.	Baseline and Week 16
Percentage of Participants Achieving a Physicians Global Assessment of Disease Activity (PGA) of "Cleared" (0) or	The PGA is a 6-point scale used to measure the severity of disease at the time of the evaluation. The degree of overall lesion severity was evaluated using the following categories: • 0 (Cleared): No evidence of scaling, erythema, or plaque elevation; • 1 (Minimal): Occasional fine scale over <5% of lesions, faint erythema, minimal plaque elevation;	Week 16

"Minimal" (1) at Week 16	• 2 (Mild): Fine scale dominates, light red coloration, mild plaque elevation; • 3 (Moderate): Course scale dominates, moderate red coloration, moderate plaque elevation; • 4 (Marked): Thick non-tenacious scale dominates, bright red coloration, marked plaque elevation; • 5 (Severe): Very thick tenacious scale predominates, dusky to deep red coloration, severe plaque elevation. The percentage of participants achieving a score of clear (0) or minimal (1) is reported.	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Who Achieved a PASI 90 Response at Week 16	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 (no psoriasis) to 72 (very severe psoriasis). A PASI 90 response is at least a 90% reduction (improvement) from Baseline in PASI score at Week 16.	Baseline and Week 16
Percentage of Participants Who Achieved a PASI 100 Response at Week 16	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	Baseline and Week 16

	ranges from 0 (no psoriasis) to 72 (very severe psoriasis). A PASI 100 response is a 100% reduction (improvement) from Baseline in PASI score at Week 16.	
Change From Baseline in the Childrens Dermatology Life Quality Index (CDLQI) Score at Week 16	The Childrens Dermatology Life Quality Index (CDLQI) is a 10-item questionnaire to measure the quality of life in children aged from 4 to 16 years. Each question is scored from 0 (not at all) to 3 (very much). 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 more quality of life is impaired.	Baseline and Week 16
Change From Baseline in the Pediatric Quality of Life Inventory (PedsQL) Score at Week 16	The PedsQL Measurement Model measures health-related quality of life (HRQOL) in children and adolescents. The 23-item PedsQL Generic Core Scale includes Physical, Emotional, Social, School Functioning dimensions. Each item is scored from 0 (never) to 4 (almost always). Items are reversed scored and linearly transformed to a 0-100 scale, so that higher scores indicate better HRQOL; the total score therefore ranges from 0 (worst) to 100 (best).	Baseline and Week 16
Percentage of Participants Achieving a PGA of "Cleared" (0) or "Minimal" (1) Upon Re-Treatment in Period C	The PGA is a 6-point scale used to measure the severity of disease at the time of the evaluation. The degree of overall lesion severity was evaluated using the following categories: 0 (Cleared): No evidence of scaling, erythema, or plaque elevation; 1 (Minimal): Occasional fine scale over < 5% of lesions, faint erythema, minimal plaque elevation; 2 (Mild): Fine scale dominates, light red coloration, mild plaque elevation; 3 (Moderate): Course scale dominates, moderate red coloration, moderate plaque elevation; 4 (Marked): Thick non-tenacious scale	Period C, Week 16

	dominates, bright red coloration, marked plaque elevation; 5 (Severe): Very thick tenacious scale predominates, dusky to deep red coloration, severe plaque elevation. The percentage of participants achieving a score of clear (0) or minimal (1) is reported.	
Time to Loss of Disease Control for Participants Who Entered Period B	Loss of disease control was defined as a worsening of PGA scores in comparison to Week 16 of Period A by at least 2 grades after treatment withdrawal. The PGA is a 6-point scale used to measure the severity of disease at the time of the evaluation. Scores range from 0 (no evidence of scaling, erythema, or plaque elevation) to 5 (very thick tenacious scale predominates, dusky to deep red coloration, severe plaque elevation). Participants who did not lose disease control in period B continued off drug into period D and were observed off-drug until they finally lost disease control or until the end of the 52 weeks of period D.	Period B (36 weeks) and Period D (52 weeks)
Percentage of Participants Achieving a PGA of "Cleared" (0) or "Minimal" (1) Over Time	The PGA is a 6-point scale used to measure the severity of disease at the time of the evaluation. The degree of overall lesion severity was evaluated using the following categories: 0 (Cleared): No evidence of scaling, erythema, or plaque elevation; 1 (Minimal): Occasional fine scale over <5% of lesions, faint erythema, minimal plaque elevation; 2 (Mild): Fine scale dominates, light red coloration, mild plaque elevation; 3 (Moderate): Course scale dominates, moderate red coloration, moderate plaque elevation; 4 (Marked): Thick non-tenacious scale dominates, bright red coloration, marked plaque elevation; 5 (Severe): Very thick tenacious scale predominates, dusky to deep red coloration,	Period A, Weeks 4, 8 and 11, Period C, Weeks 0 and 16, Period D, Weeks 0, 16, 28, 40 and 52

	severe plaque elevation. The percentage of participants achieving a score of clear (0) or minimal (1) is reported.	
Percentage of Participants Achieving a PGA of "Cleared" (0) Over Time	The PGA is a 6-point scale used to measure the severity of disease at the time of the evaluation. The degree of overall lesion severity was evaluated using the following categories: 0 (Cleared): No evidence of scaling, erythema, or plaque elevation; 1 (Minimal): Occasional fine scale over <5% of lesions, faint erythema, minimal plaque elevation; 2 (Mild): Fine scale dominates, light red coloration, mild plaque elevation; 3 (Moderate): Course scale dominates, moderate red coloration, moderate plaque elevation; 4 (Marked): Thick non-tenacious scale dominates, bright red coloration, marked plaque elevation; 5 (Severe): Very thick tenacious scale predominates, dusky to deep red coloration, severe plaque elevation. The percentage of participants achieving a score of clear (0) is reported.	Period A, Weeks 4, 8, 11 and 16, Period C, Weeks 0 and 16, Period D, Weeks 0, 16, 28, 40 and 52
Percentage of Participants Who Achieved a PASI 50 Response Over Time	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 (no psoriasis) to 72 (very severe psoriasis). A PASI 50 response is at least a 50% reduction (improvement) from Baseline in PASI score.	Baseline, Period A, Weeks 4, 8, 11 and 16, Period C, Weeks 0 and 16, Period D, Weeks 0, 16, 28, 40 and 52

Percentage of Participants Who Achieved a PASI 75 Response Over Time	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 (no psoriasis) to 72 (very severe psoriasis). A PASI 75 response is at least a 75% reduction (improvement) from Baseline in PASI score.	Baseline, Period A, Weeks 4, 8, and 11, Period C, Weeks 0 and 16, Period D, Weeks 0, 16, 28, 40 and 52
Percentage of Participants Who Achieved a PASI 90 Response Over Time	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 (no psoriasis) to 72 (very severe psoriasis). A PASI 90 response is at least a 90% reduction (improvement) from Baseline in PASI score.	Baseline, Period A, Weeks 4, 8 and 11, Period C, Weeks 0 and 16, Period D, Weeks 0, 16, 28, 40 and 52
Percentage of Participants Who Achieved a PASI 100 Response Over Time	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 (no psoriasis) to 72 (very severe psoriasis).	Baseline, Period A, Weeks 4, 8, and 11, Period C, Weeks 0 and 16, Period D, Weeks 0,

	A PASI 100 response is a 100% reduction (improvement) from Baseline in PASI score.	16, 28, 40 and 52
Percent Change From Baseline in PASI Score Over Time	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 (no psoriasis) to 72 (very severe psoriasis).	Baseline, Period A, Weeks 4, 8, 11 and 16, Period C, Weeks 0 and 16, Period D, Weeks 0, 16, 28, 40 and 52
Change From Baseline in CDLQI Over Time	The Childrens Dermatology Life Quality Index (CDLQI) is a 10-item questionnaire to measure the quality of life in children aged from 4 to 16 years. Each question is scored from 0 (not at all) to 3 (very much). 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 more quality of life is impaired.	Baseline, Period A, Weeks 4, and 8, Period C, Weeks 0 and 4, Period D, Weeks 0, 11, 28, and 52

Percentage of Participants With CDLQI = 0 Over Time	The Childrens Dermatology Life Quality Index (CDLQI) is a 10-item questionnaire to measure the quality of life in children aged from 4 to 16 years. Each question is scored from 0 (not at all) to 3 (very much). 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 more quality of life is impaired and a score of 0 indicates no impairment in quality of life.	Period A, Weeks 4, 8 and 16, Period C, Weeks 0 and 4, Period D, Weeks 0, 11, 28, and 52
Time to PASI 50/75/90/100 Response in Period A	Participants who did not have a response during Period A were censored.	Period A, 16 weeks
Change From Baseline in PedsQL Over Time	The PedsQL Measurement Model measures health-related quality of life (HRQOL) in children and adolescents. The 23-item PedsQL Generic Core Scale includes Physical, Emotional, Social, School Functioning dimensions. Each item is scored from 0 (never) to 4 (almost always). Items are reversed scored and linearly transformed to a 0-100 scale, so that higher scores indicate better HRQOL; the total score therefore ranges from 0 (worst) to 100 (best).	Baseline, Period A, Weeks 4 and 8, Period C, Weeks 0 and 4, Period D, Weeks 0, 11, 28, and 52
Change From Baseline in the Childrens Depression Inventory: Short (CDI:S)	The CDI:S is a short 10-item self-rated symptom-oriented scale used to screen for depressive symptoms. CDI:S scores range from 0 to 100, with a lower score indicating fewer depressive symptoms.	Baseline, Period A, Weeks 4, 8, and 16

Collaborators and Investigators

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

Sponsor

AbbVie (prior sponsor, Abbott)

Collaborators

No information provided

Investigators

- Study Director: David A 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

2010-12-01

First Submitted that Met QC Criteria

2010-12-01

First Posted (Estimated)
2010-12-02

Results Reporting Dates

Results First Submitted
2016-12-16

Results First Submitted that Met QC Criteria
2017-02-17

Results First Posted
2017-04-04

Study Record Updates

Last Update Submitted that met QC Criteria
2017-08-25

Last Update Posted
2017-09-25

Last Verified
2017-08

More Information

Terms related to this study

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

Randomized
Double blind
Chronic plaque psoriasis
Pediatric

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
Adalimumab
Methotrexate

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)