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

General Publications

No publications available

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

Study Record Dates

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

Study Registration Dates

First Submitted
2011-11-30

First Submitted that Met QC Criteria
2011-11-30

First Posted (Estimated)
2011-12-02

Results Reporting Dates

Results First Submitted
2015-01-20

Results First Submitted that Met QC Criteria
2015-02-09

Results First Posted (Estimated)
2015-02-20

Study Record Updates

Last Update Submitted that met QC Criteria

2015-02-09

Last Update Posted (Estimated)

2015-02-20

Last Verified

2015-02

More Information

Terms related to this study

Keywords Provided by ApoPharma

Mild to Moderate Chronic Plaque Psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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

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

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

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

COMPLETED

The Purpose of This Study is to Demonstrate the Safety and Effectiveness of Calcipotriene Foam in Subjects With Scalp and Body Psoriasis

ClinicalTrials.gov ID NCT01139580

Sponsor Stiefel, a GSK Company

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

Last Update Posted 2017 01 18

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to determine the safety and effectiveness in the treatment of psoriasis on the scalp and on the body.

Feedback

Detailed Description

The study subjects must have moderate psoriasis of the body and scalp with an ISGA of 3 at baseline. In addition, the subjects must have an evaluable target lesion of at least 2 cm^2 on the body with a score of 2 or 3 for erythema, scaling and plaque. All subjects will apply Calcipotriene Foam, 0.005% or vehicle foam topically twice a day (am and pm) to all psoriatic lesions on the body and scalp. Study visits will occur at baseline (day 1) and at weeks 1, 2, 4, and 8.

Official Title

A Multicenter, Randomized, Double Blind Study of the Safety and Efficacy of Calcipotriene Foam, 0.005%, Versus Vehicle Foam In The Treatment Of Moderate Plaque Type Scalp And Body Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Calcipotriene Foam
- Drug: Vehicle Foam

Other Study ID Numbers

- 114743
- U0267 303 (Other Identifier) (OTHER: Stiefel)

Study Start

2010 05

Primary Completion (Actual)

2010 12

Study Completion (Actual)

2010 12

Enrollment (Actual)

363

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

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

Contacts and Locations

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

United States

Arizona Locations

Tucson, Arizona, United States, 85791
Genova Clinical Research

California Locations

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

- Capable of understanding and willing to provide signed and dated written voluntary informed consent (and any local or national authorization requirements) before any protocol specific procedures are performed.
- Male or female subjects at least 12 years old and in good general health.
- Able to complete the study and to comply with study instructions.
- Moderate plaque type psoriasis on the body (excluding the scalp and face) defined as:
    - Plaque type psoriasis involving 3% to 10% of total body surface area (BSA).
    - An Investigator s Static Global Assessment (ISGA) score of 3 at Baseline.
    - Identification of a target lesion (>2 cm^2) on the trunk or extremities with a score of 2 or 3 (0 5 scale) for erythema, scaling and plaque thickness. Lesions on the palms/soles, knees, elbow, and intertriginous areas should not be used as the target lesion site.
- Involvement of at least 10% of the total scalp surface area with clinical signs (erythema, thickness, and scaliness) rated as moderate (3) based on the ISGA.
- Negative urine pregnancy test for females of childbearing potential. • Sexually active females of childbearing potential participating in the study must agree to use a medically acceptable method of contraception while receiving protocol assigned product. A woman of childbearing potential is defined as one who is biologically capable of becoming pregnant; including perimenopausal women who are fewer than 2 years from their last menses.

Exclusion Criteria:

- Any subject who has participated in any previous calcipotriene foam clinical.
- Female who is pregnant, trying to become pregnant, or breastfeeding.
- 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.
- Other serious skin disorder or any chronic medical condition that is not well controlled.
- Use of nonbiologic systemic anti psoriatic therapy (eg, corticosteroids, psoralen combined with exposure to ultraviolet light A [PUVA], ultraviolet light B [UVB], retinoids, methotrexate, cyclosporine, other immunosuppressive agents) within 4 weeks prior to enrollment.
- Systemic treatment with biological therapies (marketed or not marketed) with a possible effect on psoriasis within 4 weeks (etanercept), 2 months (adalimumab, alefacept, infliximab), 4 months (ustekinumab) or 4 weeks/5 half lives (whichever is longer) for experimental products prior to randomization.
- Use of topical therapies that have a known beneficial effect on psoriasis, including but not limited to corticosteroids, retinoids, Vitamin D derivatives, coal tar, or anthralin, within 2 weeks prior to enrollment.

- Systemic medications for other medical conditions that are known to affect psoriasis (eg, lithium, beta adrenergic blockers) within 4 weeks prior to enrollment.
- Use of any investigational product within 4 weeks prior to enrollment, currently participating in another clinical trial, or plans to receive an investigational product during the study.
- Current drug or alcohol abuse (drug screening not required).
- Has a history of any immuno compromizing disease.
- Any other condition that, in the judgment of the investigator, would put the subject at unacceptable risk for participation in the study.
- Employees of the investigator; study center; or Stiefel, a GSK company involved in the study; or an immediate family member (eg, partner, offspring, parents, siblings or sibling s offspring) of an employee involved in the study.

Ages Eligible for Study

12 Years and older (Child, Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

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

How is the study designed?

Design Details

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

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Calcipotriene Foam Calcipotriene Foam 0.005%,	Drug: Calcipotriene Foam • Calcipotriene Foam 0.005%. All treatments will be administered to the skin twice daily (am-pm) for 8 weeks for subjects in this group
Placebo Comparator: Vehicle Foam Vehicle Foam	Drug: Vehicle Foam • Vehicle Foam. All treatments will be administered to the skin twice daily (am-pm) for 8 weeks for subjects in this group

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With an Investigator s Static Global Assessment (ISGA) Score of Clear (0) or Almost Clear (1) for Scalp Involvement at Week 8 Using	The investigator assessed participants with scalp psoriasis using the ISGA, scored as (as a visual average of lesions): 0, absence of disease; 1, very mild disease, lesions (L) with minimum erythema; 2, mild disease, L with light-red coloration, slight thickness, and fine, thin scale layer; 3, moderate disease, L with red coloration, moderate thickness, and a moderate scaled layer; 4, severe disease, L with red coloration, severe thickness, and a severe coarse, thick scale layer; 5, very severe disease, L with red coloration, very severe thickness, and a very severe, coarse, thick scale layer.	Week 8

the Failure Method		
Number of Participants With an ISGA Score of Clear (0) or Almost Clear (1) for Scalp Involvement at Week 8 Using Last Observation Carried Forward (LOCF)	The investigator assessed participants with scalp psoriasis using the ISGA, scored as (as a visual average of lesions): 0, absence of disease; 1, very mild disease, lesions (L) with minimum erythema; 2, mild disease, L with light-red coloration, slight thickness, and fine, thin scale layer; 3, moderate disease, L with red coloration, moderate thickness, and a moderate scaled layer; 4, severe disease, L with red coloration, severe thickness, and a severe coarse, thick scale layer; 5, very severe disease, L with red coloration, very severe thickness, and a very severe, coarse, thick scale layer.	Week 8

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With a Target Lesion Score of 0 or 1 for Erythema and at Least a 2 Grade Improvement From Baseline at Week 8	Erythema is redness of the skin, caused by increased blood flow in the capillaries in the lower layers of the skin. The investigator assessed participants with erythema at target lesions using the psoriasis grading scale for target lesions (PGSTL). PGSTL scores: 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.	Baseline and Week 8
Number of Participants With a Target Lesion Score of 0 or 1 for Scaling and at Least a 2 Grade	Scaling of the skin is the loss of the outer layer of the epidermis in scale-like flakes. The investigator assessed participants with scaling at target lesions using the psoriasis grading scale for target lesions (PGSTL). PGSTL scores: 0, no evidence of scaling; 1, minimal, occasional fine scale over less than 5% of the lesion; 2, mild,	Baseline and Week 8

Improvement From Baseline at Week 8	fine scales predominate; 3, moderate, coarse scales predominate; 4 marked, thick non-tenacious scale predominates; 5 severe, very thick tenacious scale predominates.	
Number of Participants With a Target Lesion Score of 0 or 1 for Plaque Thickness at Week 8	Psoriasis is a noncontagious skin disorder, most often appearing as inflamed, thickened skin covered with silvery white scales on the scalp, trunk, and limbs. The investigator assessed participants with plaque thickness at target lesions using the PGSTL scores: 0, no elevation over normal skin; 1, possible but difficult to ascertain whether there is a slight elevation above normal skin; 2, slight but definite elevation, edges are indistinct or sloped; 3, moderate elevation with rough or sloped edges; 4, marked elevation with hard or sharp edges; 5, very marked elevation with hard sharp edges.	Baseline and Week 8
Number of Participants With an ISGA Score of Clear (0) or Almost Clear (1) for Body Involvement at Week 8	The investigator assessed participants with psoriasis with body involvement using the ISGA, scored as: 0, clear, minor residual discoloration, no erythema, scaling, or plaque thickness; 1, almost clear, occasional fine scale, faint erythema, and barely perceptible plaque thickness; 2, mild, fine scales predominate with light-red coloration and mild plaque thickness; 3, moderate, coarse scales predominate with moderate red coloration and plaque thickness; 4 severe, thick tenacious scale predominates with deep red coloration and severe plaque thickness. Scores are a visual average of lesions.	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
2010-06-06

First Submitted that Met QC Criteria
2010-06-07

First Posted (Estimated)
2010-06-08

Results Reporting Dates

Results First Submitted
2011-08-18

Results First Submitted that Met QC Criteria
2011-08-18

Results First Posted (Estimated)
2011-09-23

Study Record Updates

Last Update Submitted that met QC Criteria
2016-11-30

Last Update Posted (Estimated)
2017-01-18

Last Verified
2016-11

More Information

Terms related to this study

Keywords Provided by GlaxoSmithKline (Stiefel, a GSK Company)

Plaque Psoriasis
Psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Dermatologic Agents
Calcipotriene

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

   Information Identifier

   114743

   Information Comments

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

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

   Information Identifier

   114743

   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

   114743

   Information Comments

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

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

   Information Identifier

   114743

   Information Comments

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

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

   Information Identifier

   114743

Information Comments

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

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

Information Identifier

114743

Information Comments

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

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

Information Identifier

114743

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)

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

Go to the c ass c webs te

Record 1 of 1

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

Read our fu d sc a mer (https //c n ca tr a s gov/about s te/d sc a mer) for deta s

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)

TERM NATED

A Long Term Study To Evaluate The Safety And Tolerability Of CP-690,550 For Patients With Moderate To Severe Chronic Plaque Psoriasis

ClinicalTrials.gov ID NCT01163253

Sponsor Pfizer

Information provided by Pfizer (Respons b e Party)

Last Update Posted 2017 06 26

Study Details Tab

Study Overview

Brief Summary

The ma n object ve of th s study s to eva uate the ong term safety of CP 690,550 n pat ents be ng treated for moderate to severe chron c p aque psor as s Th s s an open abe extens on study ava ab e to pat ents who part c pated n one of the qua fy ng stud es w th CP 690,550 prov d ng entry cr ter a s met

Detailed Description

The study term nated on 08MAR2016 as t met ts object ves of character z ng ong term safety and to erab ty The study d d not term nate due to safety concerns

Official Title

A Phase 3, Mu t S te, Open Labe Study Of The Long Term Safety And To erab ty Of 2 Ora Doses Of CP 690,550 n Subjects W th Moderate To Severe Chron c P aque Psor as s

Conditions

Psor as s

Intervention / Treatment

- Drug CP 690,550
- Drug CP 690,550

Other Study ID Numbers

- A3921061

Feedback

- 2010 020002 15 (EudraCT Number)

Study Start

2010 09

Primary Completion (Actual)

2016 06

Study Completion (Actual)

2016 06

Enrollment (Actual)

2867

Study Type

ntervent ona

Phase

Phase 3

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)

Genet c and Rare D seases nformat on Center (https //rared seases nfo n h gov/gard) resources Chron c Graft Versus Host D sease (https //rared seases nfo n h gov/d seases/10964/chron c graft versus host d sease)

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

United States

Alabama Locations

Birmingham, Alabama, United States, 35209
Radian Research, nc

Birmingham, Alabama, United States, 35233
UAB Derma ology

Mobile, Alabama, United States, 36608
Horizon Research Group, nc

Arizona Locations

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

- Have part c pated n qua fy ng study w th CP 690,550 and are 18 years or o der w th d agnos s of p aque type psor as s (psor as s vu gar s)

Exc us on Cr ter a

- Non p aque or drug nduced forms of psor as s;
- Cannot d scont nue current ora , njectab e or top ca therapy for psor as s or cannot d scont nue phototherapy (PUVA or UVB)
- Any uncontro ed s gn ficant med ca cond t on

Ages Eligible for Study

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

Sexes Eligible for Study

A

Accepts Healthy Volunteers

No

Study Plan

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

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : N/A
Interventional Model : S ng e Group Ass gnment
Masking : None (Open Labe)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Exper menta Act ve Treatment The study s ant c pated to cont nue for up to at east 2 years post F rst Market Approva (FMA) n a g oba , major market A subjects w rece ve 10 mg B D of CP-690,550 for first 3 months of tr a Study has the opt on for var ab e dos ng w th 5 mg or 10 mg B D after first 3-months of treatment based on P d scret on	Drug CP-690,550 • 5 mg ora B D Drug CP-690,550 • 10 mg ora B D

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Part c pants W th Treatment-Emergent Adverse Events (AEs) and Ser ous Adverse Events (SAEs)	An AE was any untoward med ca occurrence n a part c pant who rece ved study drug w thout regard to poss b ty of causa re at onsh p An SAE was an AE resu t ng n any of the fo ow ng outcomes or deemed s gn ficant for any other reason death; n t a or pro onged npat ent hosp ta zat on; fe-threaten ng exper ence (mmed ate r sk of dy ng); pers stent or s gn ficant d sab ty/ ncapac ty; congen ta anoma y Treatment-emergent were events between first dose of study drug and up to 4 weeks after ast dose (up to 67 months) that were absent before treatment or that worsened re at ve to pretreatment state AEs nc uded both ser ous and non-ser ous adverse events	Base ne up to 4 weeks after ast dose of study drug (up to a max mum of 67 months)
Number of Adverse Events (AEs) by Sever ty	An AE was any untoward med ca occurrence attr buted to study drug n a part c pant who rece ved study drug AEs were c ass fied accord ng to the sever ty n 3 categor es a) m d AEs d d not nterfere w th part c pant's usua funct on; b) moderate AEs nterfered to some extent w th part c pant's usua funct on; c) severe AEs nterfered s gn ficant y w th part c pant's usua funct on	Base ne up to 4 weeks after ast dose of study drug (up to a max mum of 67 months)
Number of Part c pants W th Laboratory Abnorma t es	Abnorma ty cr ter a hemato ogy (hemog ob n, hematocr t, red b ood ce <0 8* ower m t of norma [LLN]; ret cu ocyte<0 5*LLN,>1 5*ULN; p ate ets<0 5*LLN,>1 75* upper m t of norma [ULN]; WBC<0 6*LLN, >1 5*ULN; ymphocytes, neutroph s, basoph s, eos noph s, monocytes<0 8*LLN; >1 2*ULN; coagu at on (prothromb n [PT], PT rat o>1 1*ULN) ver funct on (b rub n>1 5*ULN, aspartate am notransferase, a an ne am notransferase, a ka ne phosphatase, gamma GT>0 3*ULN, prote n, a bum n<0 8*LLN; >1 2*ULN, g obu n<0 5*LLN; >1 5*ULN); rena funct on (b ood urea n trogen, creat n ne>1 3*ULN); e ectro ytes(sod um<0 95* LLN; >1 05* ULN, potass um, ch or de, ca c um, b carbonate<0 9*LLN; >1 1*ULN), chem stry (g ucose<0 6*LLN; >1 5* ULN), ur na ys s (pH <4 5;>8, g ucose, ketones, prote n, b ood, urob nogen, n tr te, b rub n, eukocyte esterase>=1; RBC, WBC>=20); p ds (cho estero [C], LDL-C >1 3*ULN, HDL-C<0 8*LLN, tr g ycer des>1 3* ULN), hormones(T4, T3, T4, TSH<0 8* LLN; >1 2* ULN)	Base ne up to 4 weeks after ast dose of study drug (up to a max mum of 67 months)
Change From Base ne n Hemog ob n Leve at Month 1		Base ne, Month 1
Change From Base ne n Hemog ob n Leve at Month 3		Base ne, Month 3
Change From Base ne n Hemog ob n Leve at Month 6		Base ne, Month 6
Change From Base ne n Hemog ob n Leve at Month 12		Base ne, Month 12

Change From Base ne n Hemog ob n Leve at Month 24		Base ne, Month 24
Change From Base ne n Hemog ob n Leve at Month 36		Base ne, Month 36
Change From Base ne n Hemog ob n Leve at Month 48		Base ne, Month 48
Change From Base ne n Lymphocyte and Neutroph Count at Month 1		Base ne, Month 1
Change From Base ne n Lymphocyte and Neutroph Count at Month 3		Base ne, Month 3
Change From Base ne n Lymphocyte and Neutroph Count at Month 6		Base ne, Month 6
Change From Base ne n Lymphocyte and Neutroph Count at Month 12		Base ne, Month 12
Change From Base ne n Lymphocyte and Neutroph Count at Month 24		Base ne, Month 24
Change From Base ne n Lymphocyte and Neutroph Count at Month 36		Base ne, Month 36
Change From Base ne n Lymphocyte and Neutroph Count at Month 48		Base ne, Month 48
Change From Base ne n Creat n ne, Low Dens ty L poprote n Cho estero (LDL-C), H gh Dens ty L poprote n Cho estero (HDL-C) and Tota		Base ne, Month 1

Cho estero (TC) Leve s at Month 1		
Change From Base ne n Creat n ne, Low Dens ty L poprote n Cho estero (LDL-C), H gh Dens ty L poprote n Cho estero (HDL-C) and Tota Cho estero (TC) Leve s at Month 3		Base ne, Month 3
Change From Base ne n Creat n ne, Low Dens ty L poprote n Cho estero (LDL-C), H gh Dens ty L poprote n Cho estero (HDL-C) and Tota Cho estero (TC) Leve s at Month 6		Base ne, Month 6
Change From Base ne n Creat n ne, Low Dens ty L poprote n Cho estero (LDL-C), H gh Dens ty L poprote n Cho estero (HDL-C) and Tota Cho estero (TC) Leve s at Month 12		Base ne, Month 12
Change From Base ne n Creat n ne, Low Dens ty L poprote n Cho estero (LDL-C), H gh Dens ty L poprote n Cho estero (HDL-C) and Tota Cho estero (TC) Leve s at Month 24		Base ne, Month 24
Change From Base ne n Creat n ne, Low Dens ty L poprote n Cho estero (LDL-C), H gh Dens ty L poprote n Cho estero (HDL-C) and Tota Cho estero (TC) Leve s at Month 36		Base ne, Month 36
Change From Base ne n Creat n ne, Low Dens ty L poprote n Cho estero (LDL-C), H gh Dens ty L poprote n Cho estero (HDL-C) and Tota		Base ne, Month 48

Cho estero (TC) Leve s at Month 48		
Change From Base ne n Aspartate Am notransferase (AST) and A an ne Am notransferase (ALT) Leve s at Month 1		Base ne, Month 1
Change From Base ne n Aspartate Am notransferase (AST) and A an ne Am notransferase (ALT) Leve s at Month 3		Base ne, Month 3
Change From Base ne n Aspartate Am notransferase (AST) and A an ne Am notransferase (ALT) Leve s at Month 6		Base ne, Month 6
Change From Base ne n Aspartate Am notransferase (AST) and A an ne Am notransferase (ALT) Leve s at Month 12		Base ne, Month 12
Change From Base ne n Aspartate Am notransferase (AST) and A an ne Am notransferase (ALT) Leve s at Month 24		Base ne, Month 24
Change From Base ne n Aspartate Am notransferase (AST) and A an ne Am notransferase (ALT) Leve s at Month 36		Base ne, Month 36
Change From Base ne n Aspartate Am notransferase (AST) and A an ne Am notransferase (ALT) Leve s at Month 48		Base ne, Month 48
Number of Part c pants W th C n ca y S gn ficant	Phys ca exam nat ons nc uded genera appearance; sk n, head, eyes, ears, nose and throat; heart; ungs; abdomen; ower extrem t es (for the	Base ne up to 4 weeks after

Change From Base ne n Phys ca Exam nat on	presence of per phera edema) and ymph nodes C n ca s gn ficance of change from base ne va ues n phys ca exam nat on was based on nvest gator's d scret on	ast dose of study drug (up to a max mum of 67 months)
Number of Part c pants W th V ta S gn Abnorma t es	Cr ter a for abnorma t es n v ta s gns nc uded Systo c b ood pressure (SBP) ess than (<) 90 m meter of mercury (mmHg) and max mum ncrease from base ne (FB) of greater than or equa to (>=) 30 mmHg; d asto c b ood pressure (DBP) <50 and greater than (>) 120 mmHg and max mum FB of >=20 mmHg; heart rate <40 and >120 beats per m nute	Base ne up to 4 weeks after ast dose of study drug (up to a max mum of 67 months)
Change From Base ne n Systo c B ood Pressure (BP) and D asto c BP at Month 1		Base ne, Month 1
Change From Base ne n Systo c B ood Pressure (BP) and D asto c BP at Month 3		Base ne, Month 3
Change From Base ne n Systo c B ood Pressure (BP) and D asto c BP at Month 6		Base ne, Month 6
Change From Base ne n Systo c B ood Pressure (BP) and D asto c BP at Month 12		Base ne, Month 12
Change From Base ne n Systo c B ood Pressure (BP) and D asto c BP at Month 24		Base ne, Month 24
Change From Base ne n Systo c B ood Pressure (BP) and D asto c BP at Month 36		Base ne, Month 36
Change From Base ne n Systo c B ood Pressure (BP) and D asto c BP at Month 48		Base ne, Month 48
Change From Base ne n Heart Rate at Month 1		Base ne, Month 1
Change From Base ne n Heart Rate at Month 3		Base ne, Month 3

Change From Base ne n Heart Rate at Month 6		Base ne, Month 6
Change From Base ne n Heart Rate at Month 12		Base ne, Month 12
Change From Base ne n Heart Rate at Month 24		Base ne, Month 24
Change From Base ne n Heart Rate at Month 36		Base ne, Month 36
Change From Base ne n Heart Rate at Month 48		Base ne, Month 48
Number of Part c pants W th E ectrocard ogram (ECG) Abnorma t es	Cr ter a for ECG abnorma ty PR nterva >=300 m seconds (msec); QT nterva >=500 msec; QTcB (Bazett's Correct on) and QTcF (Fr der c a's Correct on) 450 to <480 msec, 480 to <500 msec and >=500 msec	Base ne up to 4 weeks after ast dose of study drug (up to a max mum of 67 months)
Change From Base ne n QRS Comp ex, PR, QT, QTcB, QTcF and RR nterva at Month 6		Base ne, Month 6
Change From Base ne n QRS Comp ex, PR, QT, QTcB, QTcF and RR nterva at Month 12		Base ne, Month 12
Change From Base ne n QRS Comp ex, PR, QT, QTcB, QTcF and RR nterva at Month 24		Base ne, Month 24
Change From Base ne n QRS Comp ex, PR, QT, QTcB, QTcF and RR nterva at Month 36		Base ne, Month 36
Change From Base ne n QRS Comp ex, PR, QT, QTcB, QTcF and RR nterva at Month 48		Base ne, Month 48
Number of Part c pants W th Adjud cated Card ovascu ar Events	Adjud cated card ovascu ar events were assessed by adjud cat on comm ttee as ndependent rev ewers based on event documentat on nc ud ng hosp ta d scharge summar es, operat ve reports, c n c notes, ECGs, d agnost c enzymes, resu ts of other d agnost c tests, autopsy reports and death cert ficate nformat on; as app cab e	Base ne up to 4 weeks after ast dose of study drug (up

		to a max mum of 67 months)
Number of Part c pants W th Ma gnancy Events	Ma gnancy events nc uded ymphoma, and demye nat ng neuro og c events B ops es co ected for ma gnancy events were subm tted to the centra aboratory for patho og st over-read	Base ne up to 4 weeks after ast dose of study drug (up to a max mum of 67 months)

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Part c pants Ach ev ng Phys c an G oba Assessment (PGA) Response of 'C ear' or 'A most C ear'	The PGA of psor as s was scored on a 5-po nt sca e, reflect ng a g oba cons derat on of the erythema (E), ndurat on ( ), and sca ng (S) across a psor at c es ons n part c pants The sever ty rat ng scores (Erythema 0= no ev dence of erythema to 4= dark, deep red; ndurat on 0= no ev dence of p aque e evat on to 4= marked p aque e evat on, hard/sharp borders; Sca ng 0= no ev dence of sca ng to 4= th ck, coarse sca e predom nates) were summed (E + + S = tota) and the average (tota /3) was taken The tota average was rounded to the nearest who e number score to determ ne the PGA The 5-po nt sca e for PGA was 0= c ear; 1= a most c ear; 2= m d; 3= moderate; 4= severe, where h gher score nd cated more sever ty of psor as s Percentage of part c pants w th response of 'c ear' (score of '0') and 'a most c ear' (score of '1') were reported	Month 1, 3, 6, 12, 24, 36, 48
Percentage of Part c pants Ach ev ng Greater Than or Equa to (>=) 75 Percent Reduct on From Base ne n Psor as s Area and Sever ty ndex (PAS) Scores	PAS score s the comb ned assessment of es on sever ty (est mated by 3 components of erythema, ndurat on and sca ng) and area affected nto s ng e score range 0 (no d sease) to 72 (max ma d sease), w th h gher scores represent ng greater sever ty of psor as s Each component of sever ty, that s, erythema, ndurat on and sca ng was assessed separate y for four body areas (head and neck [h], upper mbs [u], trunk [t] and ower mbs [ ]) on a 5-po nt sca e rang ng from 0=no nvo vement, 1=s ght, 2=moderate, 3=marked, 4=very marked H gher score nd cates greater sever ty F na PAS score = 0 1Ah (Eh + h + Sh) + 0 2Au (Eu + u + Su) + 0 3At (Et + t + St) + 0 4A (E + + S), where head and neck 0 1; upper mbs 0 2; trunk 0 3; ower mbs 0 4 Percentage of part c pants w th >=75 percent (%) reduct on from base ne n PAS scores were reported	Base ne, Month 1, 3, 6, 12, 24, 36, 48
Psor as s Area and Sever ty ndex (PAS) Scores	PAS score s the comb ned assessment of es on sever ty (est mated by 3 components of erythema, ndurat on and sca ng) and area affected nto s ng e score range 0 (no d sease) to 72 (max ma d sease), w th h gher scores represent ng greater sever ty of psor as s Each component of sever ty, that s, erythema, ndurat on and sca ng was assessed separate y for four body areas (head and neck [h], upper mbs [u], trunk [t] and ower mbs [ ]) on a 5-po nt sca e rang ng from 0=no nvo vement, 1=s ght, 2=moderate, 3=marked, 4=very marked H gher score nd cates greater sever ty F na PAS score = 0 1Ah (Eh + h + Sh) + 0 2Au (Eu + u + Su) + 0 3At (Et + t + St) + 0 4A (E + + S), where head and neck 0 1; upper mbs 0 2; trunk 0 3; ower mbs 0 4	Base ne, Month 1, 3, 6, 12, 24, 36, 48
Change From Base ne n Psor as s Area and Sever ty ndex (PAS)	PAS score s the comb ned assessment of es on sever ty (est mated by 3 components of erythema, ndurat on and sca ng) and area affected nto s ng e score range 0 (no d sease) to 72 (max ma d sease), w th h gher	Base ne, Month 1, 3, 6, 12, 24, 36, 48

Scores at Month 1, 3, 6, 12, 24, 36 and 48	scores represent ng greater sever ty of psor as s Each component of sever ty, that s, erythema, ndurat on and sca ng was assessed separate y for four body areas (head and neck [h], upper mbs [u], trunk [t] and ower mbs [ ]) on a 5-po nt sca e rang ng from 0=no nvo vement, 1=s ght, 2=moderate, 3=marked, 4=very marked H gher score nd cates greater sever ty F na PAS score = 0 1Ah (Eh + h + Sh) + 0 2Au (Eu + u + Su) + 0 3At (Et + t + St) + 0 4A (E + + S), where head and neck 0 1; upper mbs 0 2; trunk 0 3; ower mbs 0 4	
Psor as s Area and Sever ty ndex (PAS) Component Scores Erythema	PAS score s the comb ned assessment of es on sever ty (est mated by 3 components of erythema, ndurat on and sca ng) and area affected nto s ng e score range 0 (no d sease) to 72 (max ma d sease), w th h gher scores represent ng greater sever ty of psor as s Erythema was assessed separate y for four body areas (head and neck, upper mbs, trunk and ower mbs) on a 5-po nt sca e ranges from 0=no nvo vement, 1=s ght, 2=moderate, 3=marked, 4=very marked H gher score nd cates greater sever ty	Base ne, Month 1, 3, 6, 12, 24, 36, 48
Psor as s Area and Sever ty ndex (PAS) Component Scores ndurat on	PAS score s the comb ned assessment of es on sever ty (est mated by 3 components of erythema, ndurat on and sca ng) and area affected nto s ng e score range 0 (no d sease) to 72 (max ma d sease), w th h gher scores represent ng greater sever ty of psor as s ndurat on was assessed separate y for four body areas (head and neck, upper mbs, trunk and ower mbs) on a 5-po nt sca e ranges from 0=no nvo vement, 1=s ght, 2=moderate, 3=marked, 4=very marked H gher score nd cates greater sever ty	Base ne, Month 1, 3, 6, 12, 24, 36, 48
Psor as s Area and Sever ty ndex (PAS) Component Scores Sca ng	PAS score s the comb ned assessment of es on sever ty (est mated by 3 components of erythema, ndurat on and sca ng) and area affected nto s ng e score range 0 (no d sease) to 72 (max ma d sease), w th h gher scores represent ng greater sever ty of psor as s Sca ng was assessed separate y for four body areas (head and neck, upper mbs, trunk and ower mbs) on a 5-po nt sca e ranges from 0=no nvo vement, 1=s ght, 2=moderate, 3=marked, 4=very marked H gher score nd cates greater sever ty	Base ne, Month 1, 3, 6, 12, 24, 36, 48
Change From Base ne n Psor as s Area and Sever ty ndex (PAS) Component Scores Erythema at Month 1, 3, 6, 12, 24, 36 and 48	PAS score s the comb ned assessment of es on sever ty (est mated by 3 components of erythema, ndurat on and sca ng) and area affected nto s ng e score range 0 (no d sease) to 72 (max ma d sease), w th h gher scores represent ng greater sever ty of psor as s Erythema was assessed separate y for four body areas (head and neck, upper mbs, trunk and ower mbs) on a 5-po nt sca e ranges from 0=no nvo vement, 1=s ght, 2=moderate, 3=marked, 4=very marked H gher score nd cates greater sever ty	Base ne, Month 1, 3, 6, 12, 24, 36, 48
Change From Base ne n Psor as s Area and Sever ty ndex (PAS) Component Scores ndurat on at Month 1, 3, 6, 12, 24, 36 and 48	PAS score s the comb ned assessment of es on sever ty (est mated by 3 components of erythema, ndurat on and sca ng) and area affected nto s ng e score range 0 (no d sease) to 72 (max ma d sease), w th h gher scores represent ng greater sever ty of psor as s ndurat on was assessed separate y for four body areas (head and neck, upper mbs, trunk and ower mbs) on a 5-po nt sca e ranges from 0=no nvo vement, 1=s ght, 2=moderate, 3=marked, 4=very marked H gher score nd cates greater sever ty	Base ne, Month 1, 3, 6, 12, 24, 36, 48

Change From Base ne n Psor as s Area and Sever ty ndex (PAS) Component Scores Sca ng at Month 1, 3, 6, 12, 24, 36 and 48	PAS score s the comb ned assessment of es on sever ty (est mated by 3 components of erythema, ndurat on and sca ng) and area affected nto s ng e score range 0 (no d sease) to 72 (max ma d sease), w th h gher scores represent ng greater sever ty of psor as s Sca ng was assessed separate y for four body areas (head and neck, upper mbs, trunk and ower mbs) on a 5-po nt sca e ranges from 0=no nvo vement, 1=s ght, 2=moderate, 3=marked, 4=very marked H gher score nd cates greater sever ty	Base ne, Month 1, 3, 6, 12, 24, 36, 48
Percentage of Part c pants Ach ev ng Greater Than or Equa to (>=) 50 Percent Reduct on From Base ne n Psor as s Area and Sever ty ndex (PAS) Scores	PAS score s the comb ned assessment of es on sever ty (est mated by 3 components of erythema, ndurat on and sca ng) and area affected nto s ng e score range 0 (no d sease) to 72 (max ma d sease), w th h gher scores represent ng greater sever ty of psor as s Each component of sever ty, that s, erythema, ndurat on and sca ng was assessed separate y for four body areas (head and neck [h], upper mbs [u], trunk [t] and ower mbs [ ]) on a 5-po nt sca e rang ng from 0=no nvo vement, 1=s ght, 2=moderate, 3=marked, 4=very marked H gher score nd cates greater sever ty F na PAS score = 0 1Ah (Eh + h + Sh) + 0 2Au (Eu + u + Su) + 0 3At (Et + t + St) + 0 4A (E + + S), where head and neck 0 1; upper mbs 0 2; trunk 0 3; ower mbs 0 4 Percentage of part c pants w th >=50% reduct on from base ne n PAS scores were reported	Base ne, Month 1, 3, 6, 12, 24, 36, 48
Percentage of Part c pants Ach ev ng Greater Than or Equa to (>=) 90 Percent Reduct on From Base ne n Psor as s Area and Sever ty ndex (PAS) Scores	PAS score s the comb ned assessment of es on sever ty (est mated by 3 components of erythema, ndurat on and sca ng) and area affected nto s ng e score range 0 (no d sease) to 72 (max ma d sease), w th h gher scores represent ng greater sever ty of psor as s Each component of sever ty, that s, erythema, ndurat on and sca ng was assessed separate y for four body areas (head and neck [h], upper mbs [u], trunk [t] and ower mbs [ ]) on a 5-po nt sca e rang ng from 0=no nvo vement, 1=s ght, 2=moderate, 3=marked, 4=very marked H gher score nd cates greater sever ty F na PAS score = 0 1Ah (Eh + h + Sh) + 0 2Au (Eu + u + Su) + 0 3At (Et + t + St) + 0 4A (E + + S), where head and neck 0 1; upper mbs 0 2; trunk 0 3; ower mbs 0 4 Percentage of part c pants w th >=90% reduct on from base ne n PAS scores were reported	Base ne, Month 1, 3, 6, 12, 24, 36, 48
Percentage of Part c pants Ach ev ng Greater Than or Equa to (>=) 125 Percent ncrease From Base ne n Psor as s Area and Sever ty ndex (PAS) Scores	PAS score s the comb ned assessment of es on sever ty (est mated by 3 components of erythema, ndurat on and sca ng) and area affected nto s ng e score range 0 (no d sease) to 72 (max ma d sease), w th h gher scores represent ng greater sever ty of psor as s Each component of sever ty, that s, erythema, ndurat on and sca ng was assessed separate y for four body areas (head and neck [h], upper mbs [u], trunk [t] and ower mbs [ ]) on a 5-po nt sca e rang ng from 0=no nvo vement, 1=s ght, 2=moderate, 3=marked, 4=very marked H gher score nd cates greater sever ty F na PAS score = 0 1Ah (Eh + h + Sh) + 0 2Au (Eu + u + Su) + 0 3At (Et + t + St) + 0 4A (E + + S), where head and neck 0 1; upper mbs 0 2; trunk 0 3; ower mbs 0 4 Percentage of part c pants w th >=125% ncrease from base ne n PAS scores were reported	Base ne, Month 1, 3, 6, 12, 24, 36, 48
tch Sever ty tem (S) Scores	S assessed sever ty of tch ng due to psor as s S was a s ng e tem, hor zonta numer c rat ng sca e Part c pants were asked to rate the r 'sever ty of tch ng' due to psor as s over the past 24 hours on a numer c rat ng sca e anchored by the terms '0=no tch ng' and '10=worst poss b e tch ng' at the ends H gher scores nd cated greater sever ty of tch ng	Base ne, Month 1, 3, 6, 12, 24, 36, 48

Change From Base ne n tch Sever ty tem (S) Scores at Month 1, 3, 6, 12, 24, 36 and 48	S assessed sever ty of tch ng due to psor as s S was a s ng e tem, hor zonta numer c rat ng sca e Part c pants were asked to rate the r 'sever ty of tch ng' due to psor as s over the past 24 hours on a numer c rat ng sca e anchored by the terms '0=no tch ng' and '10=worst poss b e tch ng' at the ends H gher scores nd cated greater sever ty of tch ng	Base ne, Month 1, 3, 6, 12, 24, 36, 48
Dermato ogy L fe Qua ty ndex (DLQ) Scores	The DLQ was a va dated, se f-adm n stered, 10- tem qua ty-of- fe quest onna re that cons sted of 10 tems that assessed the mpact of sk n d sease on qua ty of fe (da y act v t es, persona re at onsh ps, symptoms and fee ngs, e sure, work and schoo , and treatment) Each quest on was scored on a sca e of 0=not at a /not re evant to 3=very much Response from a of the 10 quest ons were added to der ve the DLQ tota scores Tota DLQ scores ranges from 0=not at a to 30=very much, w th h gher scores nd cat ng greater mpa rment n qua ty of fe	Base ne, Month 1, 6, 12, 24, 36, 48
Change From Base ne n Dermato ogy L fe Qua ty ndex (DLQ) Scores at Month 1, 6, 12, 24, 36 and 48	The DLQ was a va dated, se f-adm n stered, 10- tem qua ty-of- fe quest onna re that cons sted of 10 tems that assessed the mpact of sk n d sease on qua ty of fe (da y act v t es, persona re at onsh ps, symptoms and fee ngs, e sure, work and schoo , and treatment) Each quest on was scored on a sca e of 0=not at a /not re evant to 3=very much Response from a of the 10 quest ons were added to der ve the DLQ tota scores Tota DLQ scores ranges from 0=not at a to 30=very much, w th h gher scores nd cat ng greater mpa rment n qua ty of fe	Base ne, Month 1, 6, 12, 24, 36, 48
36- tem Short-Form (SF-36) Hea th Survey Vers on 2, Acute Phys ca Component Summary Scores	The SF-36 quest onna re, vers on 2, acute was a 36- tem gener c hea th status measure SF-36 eva uated 8 hea th-re ated aspects of an nd v dua phys ca funct on ng, ro e-phys ca , bod y pa n, soc a funct on ng, menta hea th, ro e emot ona , v ta ty, and genera hea th The score range for each of the 8 hea th aspects ranged from 0 (worst) to 100 (best), w th h gher scores nd cat ng good hea th cond t on Two summary sca e scores were computed from the 8 hea th aspect scores phys ca component summary score and menta component summary score Score range for both summary sca es ranged from 0 (worst) to 100 (best), w th h gher scores nd cat ng good hea th cond t on	Base ne, Month 6, 12, 24, 36, 48
36- tem Short-Form (SF-36) Hea th Survey Vers on 2, Acute Menta Component Summary Scores	The SF-36 quest onna re, vers on 2 was a 36- tem gener c hea th status measure SF-36 eva uated 8 hea th-re ated aspects of an nd v dua phys ca funct on ng, ro e-phys ca , bod y pa n, soc a funct on ng, menta hea th, ro e emot ona , v ta ty, and genera hea th The score range for each of the 8 hea th aspects ranged from 0 (worst) to 100 (best), w th h gher scores nd cat ng good hea th cond t on Two summary sca e scores were computed from the 8 hea th aspect scores the Phys ca Component Summary and the Menta Component Summary Score range for both summary sca e ranged from 0 (worst) to 100 (best), w th h gher scores nd cat ng good hea th cond t on	Base ne, Month 6, 12, 24, 36, 48
Number of Part c pants W th Pat ent G oba Assessment (PtGA) Response of C ear or A most C ear	The PtGA eva uated the overa sk n d sease of part c pants at that po nt n t me on a s ng e- tem Part c pants prov ded the r response on a 5-po nt sca e ranges from 0=c ear, 1=a most c ear, 2=m d, 3=moderate, 4=severe H gher score nd cated greater sever ty of d sease Part c pants who prov ded the r response as c ear (score of 0) or a most c ear (score of 1) n PtGA at each spec fied v s t were reported n th s outcome measure	Base ne, Month 1, 3, 6, 12, 24, 36, 48

Euro Qua ty of L fe- 5-D mens ons (EQ-5D)-Ut ty Scores	EQ-5D part c pant rated 5-d mens on (mob ty, se f-care, usua act v t es, pa n and d scomfort, and anx ety and depress on) quest onna re to assess hea th-re ated qua ty of fe n terms of a s ng e ut ty score Each d mens on was assessed on a 3-po nt sca e (1=no prob ems, 2=some prob ems, 3=extreme prob ems, where h gher scores=worse hea th cond t on) The responses from the 5 d mens ons were used to ca cu ate a s ng e ut ty ndex va ue Scor ng formu a deve oped by EuroQo Group ass gned a ut ty va ue for each d mens on n the profi e Score was transformed and resu ts n a tota score range -0 594 to 1 000; h gher score nd cated a better hea th state	Base ne, Month 6, 12, 24, 36, 48
Euro Qua ty of L fe-5-D mens ons (EQ-5D)-V sua Ana ogue Sca e Scores (VAS)	EQ-5D VAS was a part c pant rated quest onna re to assess hea th-re ated qua ty of fe n terms of a s ng e ndex va ue t was a v sua ana ogue sca e that ranged from 0 (m n mum) to 100 (max mum), w th h gher scores nd cat ng a better hea th cond t on	Base ne, Month 6, 12, 24, 36, 48
Number of Part c pants Who Answered Psor as s Hea thcare Resource Ut zat on Quest onna re (Ps-HCRU)	Ps-HCRU was a short quest onna re des gned to assess hea thcare resource use and the mpact of psor as s on work n the first sect on, t assessed d rect costs assoc ated w th hea thcare resource use wh ch nc uded part c pant's nteract ons w th hea thcare prov ders such as genera pract t oners, dermato og sts, card o og sts, gastroentero og sts, psych atr sts, surgeons and nurses When tak ng the even ng dose of tofac t n b, part c pants were asked to answer the Ps-HCRU quest onna re on y f they had an nteract on w th a hea thcare prov der or the r work was mpacted by psor as s on that spec fied day n th s outcome measure, number of part c pants who answered Ps-HCRU at any spec fied v s ts were reported	Base ne, Month 1, 3, 6, 12, 24, 36, 48

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
2010-07-14

First Submitted that Met QC Criteria
2010-07-14

First Posted (Estimated)
2010-07-15

Results Reporting Dates

Results First Submitted
2017-05-30

Results First Submitted that Met QC Criteria
2017-05-30

Results First Posted
2017-06-26

Study Record Updates

Last Update Submitted that met QC Criteria
2017-05-30

Last Update Posted
2017-06-26

Last Verified
2017-05

More Information

Terms related to this study

Keywords Provided by Pfizer

chron c
severe
treatment
safety

CP 690,55
P aque Psor as s
Psor as s Vu gar s
Xe janz
Tofac t n b

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
Tofac t n b

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Yes

IPD Plan Description

nformat on re at ng to our po cy on data shar ng and the process for request ng data can be found at the fo ow ng nk

http //www pfizer com/research/c n ca _tr a s/tr a _data_and_resu ts/data_requests

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=A3921061&StudyName=A%20Long%20Term%20Study%20To%20Eva uate%20The%20Safety%20And%20To erab ty%20Of%20CP 690%2C550%20For%20Pat ents%20W th%20Moderate%20To%20Severe%20Chron c%20P aque%20Psor as)

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

Effects of Desoximetasone Spray 0.25% in Patients With Moderate to Severe Plaque Psoriasis

ClinicalTrials.gov ID NCT01206660

Sponsor Taro Pharmaceuticals USA

Information provided by Taro Pharmaceuticals USA (Responsible Party)

Last Update Posted 2014 07 03

Study Details Tab

Study Overview

Brief Summary

The objective of this study is to demonstrate that desoximetasone 0.25% topical spray is effective for the treatment of patients with moderate to severe plaque psoriasis.

Feedback

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

Other Study ID Numbers

- DSXS 0914

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.

United States

Pennsylvania Locations

Hazleton, Pennsylvania, United States
Investigator 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:

- 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: Desoximetasone Spray 0.25% Desoximetasone topical spray 0.25% administered to affected area twice a day for 28 days	Drug: Desoximetasone Spray 0.25% • Desoximetasone topical spray 0.25% administered to affected area twice a day for 28 days
Placebo Comparator: placebo Placebo administered to affected area twice a day for 28 days	Drug: placebo • Placebo administered to affected area twice a day for 28 days

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Clinical Success ITT	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 the three signs and symptoms (erythema, scaling and plaque elevation).	Day 28

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Physician s Global Assessment (PGA) of Psoriasis Score at Day 28.	Physician Global Assessment (PGA) of Psoriasis: score based on dermatologist s assessment of disease averaged over all lesions of face, genitals, or intertriginous area (i.e., breast fold, gluteal crease, axilla). 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.	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

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
2010-09-20

First Submitted that Met QC Criteria
2010-09-21

First Posted (Estimated)
2010-09-22

Results Reporting Dates

Results First Submitted
2014-01-22

Results First Submitted that Met QC Criteria
2014-06-03

Results First Posted (Estimated)
2014-07-03

Study Record Updates

Last Update Submitted that met QC Criteria
2014-06-03

Last Update Posted (Estimated)
2014-07-03

Last Verified
2014-06

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

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 Study of Ustekinumab to Evaluate a "Subject-tailored" Maintenance Dosing Approach in Subjects With Moderate-to-Severe Plaque Psoriasis (PSTELLAR)

ClinicalTrials.gov ID **NCT01550744**

Sponsor Janssen Biotech, Inc.

Information provided by Janssen Biotech, Inc. (Responsible Party)

Last Update Posted 2017 02 09

Study Details Tab

Study Overview

Brief Summary

Feedback

The purpose of the study is to assess the effect of extending maintenance dosing intervals beyond 12 weeks on the clinical efficacy and safety of ustekinumab in subjects with moderate to severe plaque psoriasis.

Detailed Description

In this study, a proportion of subjects will receive study agent at its recommended dose and interval (45mg for subjects less than or equal to 100kg, or 90mg for subjects greater than 100kg; every 12 weeks after 2 starter doses at Weeks 0 and 4). The majority of subjects will have the opportunity to receive study agent less frequently during the randomization period depending on the subject s response. The study consists of a 4 week screening period; a 28 week open label run in period; a double blind treatment period from Week 28 to Week 104; a 12 week post treatment period; and a 20 week safety follow up. Participants will be randomized for the double blind period into one of two study groups. Group 1 participants will receive an injection of the study medication at a 12 week dosing interval. Group 2 participants will undergo a placebo withdrawal and may receive study agents at an extended interval greater than 12 weeks. During the double blind treatment period, subjects in Groups 1 and 2 will receive placebo as necessary to maintain the blind.

Official Title

A Phase 3b, Randomized, Double blind, Active controlled, Multicenter Study to Evaluate a "Subject tailored" Maintenance Dosing Approach in Subjects With Moderate to Severe Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Ustekinumab 45 mg
- Drug: Ustekinumab 90 mg
- Drug: Placebo

Other Study ID Numbers

- CR100708
- CNTO1275PSO3009 (Other Identifier) (OTHER: Janssen Biotech, Inc)

Study Start

2012 03

Primary Completion (Actual)

2015 05

Study Completion (Actual)

2015 07

Enrollment (Actual)

478

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

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

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: 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

California Locations

- Bakersfield, California, United States
- Irvine, California, United States
- Los Angeles, 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

Key Eligibility Criteria

- Male or female
- Have had a diagnosis of plaque type psoriasis at least 6 months prior to the first administration of study agent (subjects with concurrent psoriatic arthritis may be enrolled).
- Have plaque type psoriasis covering at least 10% of their total BSA at screening and at the time of the first administration of study agent.
- Have a PGA score of ≥ 3 at screening and at the time of the first administration of study agent.

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

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: Group 1: Approved q12w maintenance regimen Active ustekinumab study agent q12 weeks with sham/placebo as necessary to maintain blind	Drug: Ustekinumab 45 mg • Form = Injection, route = subcutaneous Drug: Ustekinumab 90 mg • Form = Injection, route = subcutaneous Drug: Placebo • Form = Injection, route = subcutaneous
Experimental: Group 2: Subject-tailored fixed-interval maintenance regimen Subjects will undergo placebo withdrawal and will receive active study agent up to q24w intervals with sham/placebo injections to maintain the blind.	Drug: Ustekinumab 45 mg • Form = Injection, route = subcutaneous Drug: Ustekinumab 90 mg • Form = Injection, route = subcutaneous Drug: Placebo • Form = Injection, route = subcutaneous

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Number of Visits at Which Participants	Clinical responses for week (wk)28 sPGA responders randomized to every 12 weeks (q12wk) fixed-interval dosing (Group 1) vs.	Up to 24 weeks (Week

Achieved a Static Physician Global Assessment (PGA) Score of Cleared (0) or Minimal (1)	patient-tailored fixed-interval dosing (Group 2) were assessed using the static PGA (sPGA) measure. Investigators graded psoriasis lesions for induration (0=no plaque elevation to 5=severe plaque elevation), erythema (0=no evidence of erythema to 5=dusky to deep red coloration), and scaling (0=no evidence of scaling to 5=severe scaling). The sum of the 3 scales is divided by 3 and rounded to obtain a final sPGA score, defined as 0=cleared (except for residual discoloration), 1=minimal, 2=mild, 3=moderate, 4=marked or 5=severe.	88 up to Week 112 [total 7 visits])

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Percentage of Participants With a Static PGA Score of Cleared (0) or Minimal (1) Over Time	Clinical responses for week (wk) 28 sPGA responders randomized to every 12 weeks (q12wk) fixed-interval dosing (Group 1) vs. patient-tailored fixed-interval dosing (Group 2) were assessed using the static PGA (sPGA) measure. Investigators graded psoriasis lesions for induration (0=no plaque elevation to 5=severe plaque elevation), erythema (0=no evidence of erythema to 5=dusky to deep red coloration), and scaling (0=no evidence of scaling to 5=severe scaling). The sum of the 3 scales is divided by 3 and rounded to obtain a final sPGA score, defined as 0=cleared (except for residual discoloration), 1=minimal, 2=mild, 3=moderate, 4=marked or 5=severe.	Week 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, 76, 80, 84, 88, 92, 96, 100, 104, 108, 112

The Number of Visits for Which Participants Achieved a Psoriasis Area and Severity Index (PASI) 75 Response	The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 to 72. A PASI 75 response is defined as greater than or equal to (>=) 75 percent (%) improvement in PASI score from baseline.	Up to 24 weeks (Week 88 up to Week 112 [total 7 visits])
The Percentage of Participants With a PASI 75 Response Over Time	The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 to 72. A PASI 75 response is defined as greater than or equal to (>=) 75 percent (%) improvement in PASI score from baseline.	Week 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, 76, 80, 84, 88, 92, 96, 100, 104, 108, 112

Collaborators and Investigators

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

Sponsor

Janssen Biotech, Inc.

Collaborators

No information provided

Investigators

- Study Director: Janssen Biotech, Inc. Clinical Trial, Janssen Biotech, 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
2012-03-08

First Submitted that Met QC Criteria
2012-03-08

First Posted (Estimated)
2012-03-12

Results Reporting Dates

Results First Submitted
2016-04-25

Results First Submitted that Met QC Criteria
2016-09-19

Results First Posted (Estimated)
2016-11-06

Study Record Updates

Last Update Submitted that met QC Criteria
2016-12-15

Last Update Posted (Estimated)
2017-02-09

Last Verified
2016-12

More Information

Terms related to this study

Keywords Provided by Janssen Biotech, Inc.

Psoriasis
Ustekinumab
STELARA
Skin disease
Monoclonal

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Dermatologic Agents
Ustekinumab

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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

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

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

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

COMPLETED

An Efficacy and Safety Study of Ustekinumab (CNTO 1275) in Participants With Plaque Psoriasis

ClinicalTrials.gov ID **NCT00723528**

Sponsor Janssen Pharmaceutical K.K.

Information provided by Janssen Pharmaceutical K.K. (Responsible Party)

Last Update Posted 2014 05 20

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to evaluate the safety and efficacy of ustekinumab (CNTO 1275) compared with placebo in participants with moderate to severe plaque type psoriasis.

Feedback

Detailed Description

This is a multicenter (involving more than 1 study center), randomized (study medication assigned by chance), double blind (neither the invesitigator nor the participant knows the identity of the study medication), placebo controlled (1 of the study medications is inactive), parallel group comparative study (different groups of participants will receive different treatments at the same time). The total duration of the study will be 78 weeks which will be comprised of: a screening period (6 weeks); an efficacy assessment period (64 weeks [with a total of 7 treatments at Weeks 0, 4, 12, 16, 28, 40, and 52]) and a follow up assessment period (8 weeks). The efficacy assessment period will further include: a placebo controlled treatment period (Weeks 0 12) and an active drug treatment period (Weeks 12 64). During the placebo controlled treatment period, participants will receive ustekinumab (45 mg or 90 mg) subcutaneously (SC into the muscles) or placebo SC. During the active drug treatment period, participants will continue treatment with 45 mg or 90 mg SC as assigned during the placebo controlled treatment period; however, participants in the placebo group will be divided into 2 groups and will receive ustekinumab 45 mg (Placebo A) or 90 mg (Placebo B) SC. Efficacy will be evaluated primarily by analysis of psoriasis area and severity index (PASI) score. Participant safety will also be monitored.

Official Title

A Placebo Controlled Double Blind Comparative Study of CNTO1275 in Patients With Plaque Type Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Placebo (CP)
- Drug: Ustekinumab 45 mg (CP)
- Drug: Ustekinumab 90 mg (CP)
- Drug: Placebo A (After CP)
- Drug: Placebo B (After CP)
- Drug: Ustekinumab 45 mg (After CP)
- Drug: Ustekinumab 90 mg (After CP)

Other Study ID Numbers

- CR015166
- JNS009 JPN 02

Study Start

2008 03

Primary Completion (Actual)

2009 01

Study Completion (Actual)

2010 03

Enrollment (Actual)

158

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.

Japan

- Asahikawa, Japan
- Chitose, Japan
- Chuo, Japan

Fukuoka, Japan

Fushimi, Japan

Isehara, Japan

Kanazawa, Japan

Kurume, Japan

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:

- Participants diagnosed with psoriasis (psoriasis vulgaris and psoriatic arthritis) at least 6 months before registration
- Participants with plaque type psoriasis covering at least 10 percent of total body surface area at the time of informed consent and at registration
- Participants with a PASI score of greater than or equal to 12 at the time of informed consent and at registration
- Female participants of childbearing potential or males, whose partner can be pregnant, must agree that he/she will continuously take an appropriate contraceptive measure for 1 year from the day of informed consent to termination of the final investigational treatment; in the case of childbearing potential females, pregnancy test at screening must be negative
- Participants must agree not to receive Bacillus Calmette Guérin (BCG) vaccination and live vaccine inoculation for 1 year after final treatment with the investigational product

Exclusion Criteria:

- Participants with guttate psoriasis, erythrodermic psoriasis, or pustular psoriasis
- Participants with a medical history of tuberculosis infection or suspected tuberculosis infection
- Participants with present or past history of chronic or recurrent infection (e.g., chronic or recurrent urinary tract infection or respiratory infection)
- Participants with a current serious infection (e.g., sepsis, hepatitis, pneumonia, or pyelonephritis) or those who experienced a serious infection within the 2 month period before registration and including participants who received intravenous administration of antibiotics or antiviral agents within the 2 month period before registration
- Participants with a current or past history of malignant tumors (except for basal cell carcinoma, intraepidermal squamous cell carcinoma in the skin and uterine cervical squamous cell carcinoma, whose treatment was completed and no sign suggesting a recurrence has been observed, and squamous cell carcinoma in the skin whose treatment was completed and no sign suggesting a recurrence has been observed in the past 5 years)

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 : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Placebo Comparator: Placebo (CP) Placebo 0.5 ml and 1.0 ml will be administered subcutaneously (SC) on Weeks 0 and 4 respectively during the controlled period (Weeks 0-12).	Drug: Placebo (CP) • Placebo 0.5 ml and 1.0 ml will be administered subcutaneously (SC) on Weeks 0 and 4 respectively during the controlled period (Weeks 0-12).
Active Comparator: Ustekinumab 45 mg (CP) Ustekinumab 45 mg (0.5 ml) and placebo (1.0 ml) will be administered SC on Weeks 0 and 4 during controlled period (Weeks 0-12).	Drug: Ustekinumab 45 mg (CP) • Ustekinumab 45 mg (0.5 ml) and placebo (1.0 ml) will be administered SC on Weeks 0 and 4 during controlled period (Weeks 0-12).
Active Comparator: Ustekinumab 90 mg (CP) Ustekinumab 90 mg (1.0 ml) and placebo (0.5 ml) will be administered SC on Weeks 0 and 4 during controlled period (Weeks 0-12).	Drug: Ustekinumab 90 mg (CP) • Ustekinumab 90 mg (1.0 ml) and placebo (0.5 ml) will be administered SC on Weeks 0 and 4 during controlled period (Weeks 0-12).

Placebo Comparator: Placebo A (After CP) After the controlled period (that is [i.e.], during the active drug treatment period [Weeks 12-64]), the placebo group will be randomized into 2 groups, including Placebo A, in which ustekinumab 45 mg (0.5 ml) and placebo (1.0 ml) will be administered SC at Weeks 12, 16, 28, 40, and 52.	Drug: Placebo A (After CP) • After the controlled period (i.e., during the active drug treatment period [Weeks 12-64]), the placebo group will be randomized into 2 groups, including Placebo A, in which ustekinumab 45 mg (0.5 ml) and placebo (1.0 ml) will be administered SC at Weeks 12, 16, 28, 40, and 52.
Placebo Comparator: Placebo B (After CP) After the controlled period (i.e., during the active drug treatment period [Weeks 12-64]), the placebo group will be randomized into 2 groups, including Placebo B, in which ustekinumab 90 mg (1.0 ml) and placebo (0.5 ml) will be administered SC at Weeks 12, 16, 28, 40, and 52.	Drug: Placebo B (After CP) • After the controlled period (i.e., during the active drug treatment period [Weeks 12-64]), the placebo group will be randomized into 2 groups, including Placebo B, in which ustekinumab 90 mg (1.0 ml) and placebo (0.5 ml) will be administered SC at Weeks 12, 16, 28, 40, and 52.
Active Comparator: Ustekinumab 45 mg (After CP)	Drug: Ustekinumab 45 mg (After CP) • After the controlled period (i.e., during the active drug treatment period [Weeks 12-

After the controlled period (i.e., during the active drug treatment period [Weeks 12-64]), participants in the ustekinumab 45 mg group will receive placebo (0.5 ml and 1.0 ml) SC at Week 12 followed by ustekinumab 45 mg (0.5 ml) and placebo (1.0 ml) SC at Weeks 16, 28, 40 and 52.	64]), participants in the ustekinumab 45 mg group will receive placebo (0.5 ml and 1.0 ml) SC at Week 12 followed by ustekinumab 45 mg (0.5 ml) and placebo (1.0 ml) SC at Weeks 16, 28, 40 and 52.
Active Comparator: Ustekinumab 90 mg (After CP) After the controlled period (i.e., during the active drug treatment period [Weeks 12-64]), participants in the ustekinumab 90 mg group will receive placebo (0.5 ml and 1.0 ml) SC at Week 12 followed by ustekinumab 90 mg (1.0 ml) and placebo (0.5 ml) SC at Weeks 16, 28, 40 and 52.	Drug: Ustekinumab 90 mg (After CP) • After the controlled period (i.e., during the active drug treatment period [Weeks 12-64]), participants in the ustekinumab 90 mg group will receive placebo (0.5 ml and 1.0 ml) SC at Week 12 followed by ustekinumab 90 mg (1.0 ml) and placebo (0.5 ml) SC at Weeks 16, 28, 40 and 52.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Percentage of Participants With Greater Than or Equal to 75 Percent (%) Improvement in Psoriasis Area and Severity Index (PASI) Score	Percentage of participants with >=75% improvement in PASI score at Week 12 from Baseline was reported. PASI is a widely used tool for the measurement of severity of psoriasis. The combination of redness, scaling, and thickness, as well as overall body involvement determine the PASI score. The scale ranges from 0 (best) to 72 (worst). Baseline visit refers to Week 0.	Week 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Baseline in Dermatology Life Quality Index (DLQI) Score at Week 12	The DLQI is a self-administered 10-item questionnaire that is used to assess 6 different aspects of quality of life: symptoms and feelings, daily activities, leisure, work or school performance, personal relationships, and treatment. Scores range from 0 (no impairment in quality of life) to 30 (most impairment in quality of life).	Week 12
Psoriasis Area and Severity Index (PASI) Score	PASI is a widely used tool for the measurement of severity of psoriasis. The combination of redness, scaling, and thickness, as well as overall body involvement determine the PASI score. The scale ranges from 0 (best) to 72 (worst).	Week 64
Percentage of Treatment Response Based on Psoriasis Area and Severity Index (PASI) Score	PASI is a widely used tool for the measurement of severity of psoriasis. The combination of redness, scaling, and thickness, as well as overall body involvement determine the PASI score. The scale ranges from 0 (best) to 72 (worst). Percentage of Treatment Response= (Baseline PASI score-PASI score after treatment)/Baseline PASI score x 100. Baseline visit refers to Week 0.	Week 64

Percentage of Participants With Greater Than or Equal to (>=) 50 Percent (%), 90%, and Equal to 100% of Treatment Response Based on PASI Score	PASI is a widely used tool for the measurement of severity of psoriasis. The combination of redness, scaling, and thickness, as well as overall body involvement determine the PASI score. The scale ranges from 0 (best) to 72 (worst). Percentage of Treatment Response= (Baseline PASI score-PASI score after treatment)/Baseline PASI score x 100. Baseline visit refers to Week 0.	Week 64
Change From Baseline in Dermatology Life Quality Index (DLQI) Score at Week 28, 40, 52 and 64	The DLQI is a self-administered 10-item questionnaire that is used to assess 6 different aspects of quality of life: symptoms and feelings, daily activities, leisure, work or school performance, personal relationships, and treatment. Scores range from 0 (no impairment in quality of life) to 30 (most impairment in quality of life).	Week 28, 40, 52 and 64
Change From Baseline in 36-Item Short Form Health Survey (SF-36) at Week 12, 28, 40, 52 and 64	The SF-36 is a validated instrument measuring health-related quality of life across multiple disease states. It has 36 questions with 8 subscale scores and 2 summary scores: (1) physical component summary (PCS)=physical functioning, role-physical, bodily pain, and general health; (2) mental component summary (MCS)=vitality, social functioning, role-emotional, and mental health. There is no total overall score; scoring is done for both sub scores and summary scores. For sub scores and summary scores: 0=worst score and 100=best score.	Week 12, 28, 40, 52 and 64
Change From Baseline in Psoriasis Disability Index (PDI) Score at	The PDI questionnaire consists of 15 questions relating to the impact of psoriasis in terms of daily activities, work or school, personal relationships, leisure, and treatment. Each question is scored on a scale of 0 (no impact) to	Week 12, 28, 40, 52 and 64

Week 12, 28, 40, 52 and 64	3 (greatest impact). The PDI is calculated by summing the scores of the questions resulting in a maximum score of 45 (greatest impact) and a minimum score of 0 (no impact).	
Treatment Response Based on Nail Psoriasis Severity Index (NAPSI) Score	The NAPSI score is used to evaluate the severity of nail bed psoriasis and nail matrix psoriasis. The nail is divided with into quadrants and given a score for nail bed psoriasis (0-4) and nail matrix psoriasis (0-4) depending on the presence of any of the features of nail psoriasis in that quadrant. Each nail is evaluated, and the sum of all the nails is the total NAPSI score. The sum of the scores from all nails ranges from 0 (no psoriasis) to 80 (psoriasis present in all 4 quadrants of all 10 nails).	Week 12, 28, 40,52 and 64
Change From Baseline in the Number of Nails With Psoriasis Involvement at Week 12, 28, 40, 52 and 64	The number of nails with psoriasis involvement was assessed by a dermatologist.	Week 12, 28, 40, 52 and 64
Change From Baseline in Joint Symptoms Expressed on a Visual Analogue Scale (VAS) at Week 12, 28, 40, 52 and 64	Each participant will assess his/her pain associated with joint symptoms on each assessment day using a 100 mm VAS ranging from 0 mm (no pain) to 100 mm (the worst pain imaginable).	Week 12, 28, 40, 52 and 64
Percentage of Participants With Cleared (0), Cleared or Minimal (0 or 1) and Mild (Less	Percentage of participants with PGA score of cleared (0), cleared or minimal (0 or 1) and mild (less than or equal to 2) was reported. The PGA score is a numeric scale which is completed by the physician and is designed to evaluate the physician s overall assessment of the	Week 12

Than or Equal to 2) Physicians Global Assessment (PGA) Score at Week 12	participants psoriasis. Overall lesions will be graded for induration (I), erythema (E), and scaling (S) as: 0=cleared, 1=minimal, 2=mild, 3=moderate, 4=marked, and 5=severe. The sum of the 3 scores (I + E + S) will be divided by 3 to obtain a final PGA score ranging from 0 [best] to 5 [worst].	
Percentage of Participants With Cleared (0), Cleared or Minimal (0 or 1) and Mild (Less Than or Equal to 2) Physicians Global Assessment (PGA) Score at Week 64	Percentage of participants with PGA score of cleared (0), cleared or minimal (0 or 1) and mild (less than or equal to 2) was reported. The PGA score is a numeric scale which is completed by the physician and is designed to evaluate the physicians overall assessment of the participants psoriasis. Overall lesions will be graded for induration (I), erythema (E), and scaling (S) as: 0=cleared, 1=minimal, 2=mild, 3=moderate, 4=marked, and 5=severe. The sum of the 3 scores (I + E + S) will be divided by 3 to obtain a final PGA score ranging from 0 [best] to 5 [worst].	Week 64

Collaborators and Investigators

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

Sponsor

Janssen Pharmaceutical K.K.

Collaborators

No information provided

Investigators

- Study Director: Janssen Pharmaceutical K.K. Clinical Trial, Janssen Pharmaceutical K.K.

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
2008-07-24

First Submitted that Met QC Criteria
2008-07-25

First Posted (Estimated)
2008-07-28

Results Reporting Dates

Results First Submitted
2013-12-02

Results First Submitted that Met QC Criteria
2014-04-22

Results First Posted (Estimated)
2014-05-20

Study Record Updates

Last Update Submitted that met QC Criteria

2014-04-22

Last Update Posted (Estimated)

2014-05-20

Last Verified

2014-04

More Information

Terms related to this study

Keywords Provided by Janssen Pharmaceutical K.K.

Psoriasis
Ustekinumab
CNTO 1275

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Dermatologic Agents
Ustekinumab

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by Janssen Pharmaceutical K.K.

Week 28 data cut off Clinical Study Report for a Placebo Controlled Double Blind Study of CNTO 1275 in Subjects with Plaque Psoriasis (http://filehosting.pharmacm.com/DownloadService.ashx?client=CTR_JNJ_6051&studyid=425&filename=CR015166_w28CSR.pdf)

|Final Clinical Study Report for A Placebo Controlled Double Blind Study of CNTO 1275 in Subjects with Plaque Psoriasi (http://filehosting.pharmacm.com/DownloadService.ashx?

client=CTR_JNJ_6051&studyid=425&filename=CR015166_finalCSR.pdf)

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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

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

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

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

COMPLETED

An Efficacy and Safety Study of CNTO 1275 Compared to Etanercept in Patients With Plaque Psoriasis

ClinicalTrials.gov ID **NCT00454584**

Sponsor Centocor, Inc.

Information provided by Centocor, Inc. (Responsible Party)

Last Update Posted 2012 11 21

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to compare the efficacy and safety of CNTO 1275 to etanercept in patients with moderate to severe plaque psoriasis.

Feedback

Detailed Description

This is a multicenter, randomized (study medication assigned by chance), active controlled, parallel, 3 arm study. Patients will be randomly (allocation to treatments available by chance) assigned in 3:5:5 ratio to receive one of three treatments groups. The three treatment groups are: Group 1 CNTO 1275 45 mg dosing at weeks 0 and 4, Group 2 CNTO 1275 90 mg dosing at weeks 0 and 4, Group 3 Etanercept 50 mg two times per week through week 12. The total duration for each participant will be up to 64 weeks (approximately 16 months). The active controlled portion of the study is from Week 0 to Week 12 during which the efficacy and safety of etanercept and 2 dose levels of CNTO 1275 will be evaluated. Treatment after Week 12 is dependent on Physicians Global Assessment (PGA) response at Week 12 and initial treatment assignment. Patients will receive 2 subcutaneous injections of CNTO 1275 (either 45 or 90 mg doses) or twice weekly injections of etanercept during the first twelve weeks of the study. Patients may receive two additional doses of CNTO 1275 (either 45 or 90 mg doses) up to week 44.

Official Title

A Phase 3, Multicenter, Randomized Study Comparing CNTO 1275 and Etanercept for the Treatment of Moderate to Severe Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: CNTO 1275 45 mg
- Drug: CNTO 1275 90 mg
- Drug: Etanercept 50 mg

Other Study ID Numbers

- CR013015
- C0743T12 (Other Identifier) (OTHER: Centocor)
- 2006 003444 30 (EudraCT Number)

Study Start

2007 03

Primary Completion (Actual)

2008 01

Study Completion (Actual)

2009 01

Enrollment (Actual)

903

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

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

Contacts and Locations

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

No location data

Participation Criteria

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

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

Eligibility Criteria

Description

Inclusion Criteria:

- Have had a diagnosis of plaque type psoriasis at least 6 months prior to the study
- Have plaque type psoriasis covering at least 10 percentage of total body surface area
- Have a Psoriasis Area and Severity Index (PASI) score of 12 or greater and a Physicians Global Assessment (PGA) score of 3 or greater at the time of the first administration of study drug
- Must be suitable for phototherapy or systemic treatment for psoriasis
- Have failed to respond to or have condition which prevents use of cyclosporine, methotrexate (MTX) or psoralen plus ultraviolet light A (PUVA)

Exclusion Criteria:

- Currently have nonplaque forms of psoriasis
- Have current drug induced psoriasis
- Have used any therapeutic agent targeted at reducing interleukin 12 (IL 12) or IL 23 (Interleukins are the substance produced by body in immunological disease like psoriasis)
- Have received phototherapy or any systemic medications/treatments that could affect psoriasis or PASI evaluation (including, but not limited to, oral or injectable corticosteroids, retinoids, 1,25 dihydroxy vitamin D3 and analogues, psoralens, sulfasalazine, hydroxyurea, or fumaric acid derivatives) within 4 weeks of the first administration of study agent
- Have used a biologic within the previous 3 months

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 (Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: CNTO 1275 45 mg Patients will receive CNTO 1275 45 mg at the Weeks 0 and 4 visits. Treatment after Week 12 is dependent on Physician s Global Assessment (PGA) response at Week 12 and initial treatment assignment.	Drug: CNTO 1275 45 mg • Type=exact number, number=45, unit=mg, form=injection, route=subcutaneous
Experimental: CNTO 1275 90 mg Patients will receive CNTO 1275 90 mg at the Weeks 0 and 4 visits. Treatment after Week 12 is dependent on PGA response at Week 12 and initial treatment assignment.	Drug: CNTO 1275 90 mg • Type=exact number, number=90, unit=mg, form=injection, route=subcutaneous
Active Comparator: Etanercept 50 mg Patients will receive Etanercept 50 mg twice weekly through Week 12. Treatment after Week 12 is dependent on PGA response at Week 12	Drug: Etanercept 50 mg • Type=exact number, number=50, unit=mg, form=injection, route=subcutaneous

and initial treatment assignment.	

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants Achieving a Greater Than or Equal to 75 Percentage Improvement From Baseline in Psoriasis Area and Severity Index (PASI 75) Score at Week 12	Number of participants achieving greater than or equal to 75 percentage improvement from baseline in Psoriasis Area and Severity Index (PASI) at Week 12. PASI is the widely used tool for the measurement of severity of psoriasis. This is a test of how bad a persons psoriasis is. The combination of redness, scaling, and thickness, as well as overall body involvement determine the PASI score. The scale ranges from 0 (best) -72 (worst). Baseline visit refers to Week 0.	Baseline and Week 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With Physicians Global Assessment (PGA) of Cleared or Minimal at Week 12	Number of participants achieving a physician global assessment (PGA) (0-5) of cleared or minimal at Week 12. The PGA is 7-point scale used in clinical trial 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

Number of Participants Achieving a Greater Than or Equal to 90 Percentage Improvement From Baseline in Psoriasis Area and Severity Index (PASI 90) Score at Week 12	Number of participants achieving greater than or equal to 90 percentage improvement from baseline in Psoriasis Area and Severity Index (PASI) at Week 12. PASI is the widely used tool for the measurement of severity of psoriasis. This is a test of how bad a persons psoriasis is. The combination of redness, scaling, and thickness, as well as overall body involvement determine the PASI score. The scale ranges from 0 (best) -72 (worst).	Baseline and Week 12
Difference in Psoriasis Area Severity Index Between Week 12 and That Achieved 12 Weeks After Retreatment (Week R12)	The difference between the PASI score at Week 12 and that achieved after 12 weeks of retreatment. The PASI is the widely used tool for the measurement of severity of psoriasis. This is a test of how bad a persons psoriasis is. The combination of redness, scaling, and thickness, as well as overall body involvement determine the PASI score. The scale ranges from 0 (best) -72 (worst).	Up to Week 52. Retreatment may occur anytime between Week 16 and Week 40 depending on time of losing PGA response. Hence end of 12 weeks of retreatment would be between Week 28 and Week 52, inclusive.

Collaborators and Investigators

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

Sponsor

Centocor, Inc.

Collaborators

No information provided

Investigators

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

Publications

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

General Publications

No publications available

*** 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

2007-03-28

First Submitted that Met QC Criteria

2007-03-28

First Posted (Estimated)
2007-03-30

Results Reporting Dates

Results First Submitted
2009-10-23

Results First Submitted that Met QC Criteria
2012-10-19

Results First Posted (Estimated)
2012-11-21

Study Record Updates

Last Update Submitted that met QC Criteria
2012-10-19

Last Update Posted (Estimated)
2012-11-21

Last Verified
2012-10

More Information

Terms related to this study

Keywords Provided by Centocor, Inc.

Psoriasis
CNTO 1275
Etanercept
Immune diorder
Skin disorder

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
Dermatologic Agents
Etanercept
Ustekinumab

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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

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

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

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

COMPLETED

Efficacy and Safety of Intravenous and Subcutaneous Secukinumab in Moderate to Severe Chronic Plaque-type Psoriasis (STATURE)

ClinicalTrials.gov ID **NCT01412944**

Sponsor Novartis Pharmaceuticals

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

Last Update Posted 2015 03 18

Study Details Tab

Study Overview

Brief Summary

The study will assess the safety and efficacy of intravenous (10mg/kg) and subcutaneous (300mg) secukinumab in moderate to severe chronic plaque type psoriasis who are partial responders to secukinumab.

Feedback

Official Title

A Randomized, Double blind, Double Dummy, Multicenter Study to Assess the Safety, Tolerability and Long term Efficacy of Intravenous (10mg/kg) and Subcutaneous (300mg) Secukinumab in Subjects With Moderate to Severe Chronic Plaque type Psoriasis Who Are Partial Responders to Secukinumab

Conditions

Plaque type Psoriasis

Intervention / Treatment

- Drug: secukinumab 150mg
- Drug: secukinumab 10mg/kg i.v. regimen

Other Study ID Numbers

- CAIN457A2307
- 2011 002510 36 (EudraCT Number)

Study Start

2011 12

Primary Completion (Actual)

2013 04

Study Completion (Actual)

2013 04

Enrollment (Actual)

43

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

Florida Locations

Jacksonville, Florida, United States, 32216
Novartis Investigative Site

West Palm Beach, Florida, United States, 33409
Novartis Investigative Site

Massachusetts 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:

- Written Informed Consent must be obtained before any assessment is performed,
- Subject must be able to understand and communicate with the investigator and comply with the requirements of the study.
- Subjects must have participated in the study CAIN457A2304 and have achieved a partial response after twelve weeks of treatment with no major protocol deviations.

A partial response is defined as having achieved ≥ PASI 50 but < 75 response.

Exclusion criteria

- Pregnant women or lactating women
- Forms of psoriasis other than chronic plaque type
- Ongoing use of prohibited psoriasis treatments
- Ongoing use of other non psoriasis prohibited treatments
- Previous exposure to any biologic drug directly targeting IL 17 or the IL 17 receptor, except secukinumab in study CAIN457A2304
- Active ongoing inflammation diseases other than psoriasis that might confound the evaluation of the benefits of secukinumab therapy
- UV therapy or excessive exposure to sunlight

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

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

How is the study designed?

Design Details

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

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: AIN457 subcutaneous (s.c.) During the intravenous (I.V.) period, participants received two 150 mg s.c. injections of AIN457 at randomization and week 4, and AIN457 placebo I.V. at randomization, week 2 and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.	Drug: secukinumab 150mg • secukinumab 150mg (2 injections per dose)
Experimental: AIN457 I.V. During the I.V. period, participants received AIN457 10mg/kg I.V. at randomization, week 2 and week 4, and AIN457 placebo s.c. at randomization and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.	Drug: secukinumab 10mg/kg i.v. regimen • secukinumab 10mg/kg i.v. regimen

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants (Who Achieved a Partial Response Defined as ≥ 50% But < 75% Improvement in Psoriasis Area and Severity Index (PASI) After 12 Weeks of Treatment in Study AIN457A2304) With 75% Improvement From Baseline in PASI	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72(maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4).	Week 8
Percentage of Participants (Who Achieved a Partial Response Defined as ≥ 50% But < 75% Improvement in PASI After 12 Weeks of Treatment in Study AIN457A2304)	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. Treatment success was defined as achievement of IGA mod 2001 score of 0 or 1.	Week 8

With Investigator s Global Assessment Model 2011 (IGA Mod 2011) 0 or 1 Response		

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Achieving PASI 50/75/90/100 Response or IGA 0 or 1 Response	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 50, 75, 90 and 100 were defined as participants achieving ≥ 50%, 75%, 90% or 100% improvement from baseline. 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.	Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36 and 40
Mean Percent Change From Baseline in PASI Scores	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	Baseline, weeks 2, 4, 8, 12, 16, 20, 24, 28,

	scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). A negative mean percentage change indicates improvement.	32, 36 and 40
Percentage of Participants in Each IGA Mod 2011 Score Category	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.	Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36 and 40
Percentage of Participants Who Achieved Dermatology Life Quality Index (DLQI) of 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. A DLQI of 0 or 1 indicates no impairment or little impairment, respectively. A negative mean percentage change from baseline indicates improvement.	Baseline, Week 8, Week 16, Week 24, Week 32,up to Week 40
Mean Percent Change From Baseline in	The DLQI is a ten item general dermatology disability index designed to assess health-related quality of life in adult participants with	Baseline, weeks 8, 16, 24,

Dermatology Life Quality Index (DLQI) Scores	skin diseases such as eczema, psoriasis, acne and viral worts. 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. A negative mean percentage change from baseline indicates improvement.	32 and 40
Mean Percent Change From Baseline in EuroQOL 5-Dimension Health Status Questionnaire (EQ-5D) Health State Assessment (From 0 to 100)	The EQ-5D is an instrument used to assess a participant s health status. The instrument includes a descriptive profile and a visual analog scale (VAS). The descriptive profile includes 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension had 3 response levels: no problems, some problems and severe problems. The VAS is a vertical scale that assesses the health status from 0 (worst possible health state) to 100 (best possible health state). This outcome measures the percent change in VAS score. Positive mean percent changes indicate improvement.	Baseline, weeks 8, 16, 24, 32 and 40
Number of Participants Who Developed Anti-secukinumab Antibodies	The development of anti-secunimubab anti-bodies would decrease a participant s ability to respond to secukinumab treatment.	Baseline, weeks 12, 24 and 40
Relationship Between Response to AIN457 and	This outcome measure was not analyzed due to the small sample size of the study (43 participants).	End of study

Failed Response to Previous Biologic Psoriasis Therapy		

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
2011-08-05

First Submitted that Met QC Criteria
2011-08-08

First Posted (Estimated)
2011-08-09

Results Reporting Dates

Results First Submitted
2015-01-28

Results First Submitted that Met QC Criteria
2015-03-17

Results First Posted (Estimated)
2015-03-18

Study Record Updates

Last Update Submitted that met QC Criteria
2015-03-17

Last Update Posted (Estimated)
2015-03-18

Last Verified
2015-03

More Information

Terms related to this study

Keywords Provided by Novartis (Novartis Pharmaceuticals)

Psoriasis
plaque
inflammatory skin disease
scaly patches
AIN457
secukinumab
Moderate to severe

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

BI 655066 Dose Ranging in Psoriasis, Active Comparator Ustekinumab

ClinicalTrials.gov ID NCT02054481

Sponsor Boehringer Ingelheim

Information provided by Boehringer Ingelheim (Responsible Party)

Last Update Posted 2016 09 19

Study Details Tab

Study Overview

Brief Summary

The overall purpose of this trial is to assess clinical efficacy and safety of different subcutaneous doses of BI 655066 in adult patients with chronic plaque psoriasis in order to select doses for further clinical trials.

Feedback

Official Title

A 48 Weeks Study of Three Different Dose Regimens of BI 655066 Administered Subcutaneously in Patients With Moderate to Severe Chronic Plaque Psoriasis (Randomised, Dose ranging, Active comparator controlled (Ustekinumab), Double blind Within Dose Groups of BI 655066)

Conditions

Psoriasis

Intervention / Treatment

- Drug: BI 655066
- Drug: BI 655066
- Drug: Ustekinumab
- Drug: BI 655066

Other Study ID Numbers

- 1311.2
- 2012 004384 48 (EudraCT Number) (EUDRACT_NUMBER: EudraCT)

Study Start

2014 02

Primary Completion (Actual)

2014 11

Study Completion (Actual)

2015 07

Enrollment (Actual)

166

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: 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

California Locations

Los Angeles, California, United States
1311.2.10010 Boehringer Ingelheim Investigational Site

Florida Locations

Port Orange, Florida, United States
1311.2.10013 Boehringer Ingelheim Investigational Site

Click to view interactive map

Participation Criteria

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

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

Eligibility Criteria

Description

Inclusion criteria:

- Body Mass Index (BMI) >/= 18.5 and < 40 kg/m²
- Patients with stable moderate to severe chronic plaque type psoriasis with or without psoriatic arthritis involving >/= 10% body surface area, with disease severity PASI >/= 12 and sPGA score of moderate and above (score of at least 3) at screening visit and visit 2 (randomisation), as assessed by the investigator
- Psoriasis disease duration of at least 6 months prior to screening, as assessed by the investigator
- Patients must be candidates for systemic psoriasis treatment or phototherapy, as assessed by the investigator
- Patients must be suitable candidates for ustekinumab (Stelara®) therapy as given in the local labelling
- Patient must give informed consent and sign an approved consent form prior to any study procedures in accordance with GCP and local legislation

Exclusion criteria:

- Patients with guttate, erythrodermic, or pustular psoriasis and patients with drug induced psoriasis, as diagnosed by the investigator
- Evidence of current or previous clinically significant disease, medical condition other than psoriasis, or finding of the medical examination (including vital signs and ECG), that in the opinion of the investigator, would compromise the safety of the patient or the quality of the data. This criterion provides an opportunity for the investigator to exclude patients based on clinical judgment, even if other eligibility criteria are satisfied. (Psoriatic arthritis is not considered an exclusion criterion)
- Gastrointestinal, hepatic, renal, respiratory, cardiovascular, metabolic, immunological or hormonal disorders, diseases of the central nervous system (such as epilepsy) or psychiatric disorders or neurological disorders, or history of orthostatic hypotension, fainting spells or blackouts, that in the investigator s judgement, could jeopardize the safe conduct of the study.
- Clinically important acute or chronic infections including hepatitis and HIV.

With regards to tuberculosis the following applies:

Have signs or symptoms suggestive of current active or latent TB upon medical history, physical examination and/or a chest radiograph (both posterior anterior and lateral views, taken within 3 months prior to the first administration of study drug and read by a qualified radiologist).

Have history of latent or active TB prior to screening, except for patients who have documentation of having completed an adequate treatment regimen at least 6 months prior to the first administration of study agent.

Have positive IGRA testing (QuantiFERON TB Gold) within 2 months prior to or during screening, in which active TB has not been ruled out, except for patients with history of latent

TB and documentation of having completed an adequate treatment regimen at least 6 months prior to the first administration of study agent.

- Have had a live vaccination </= 12 weeks prior to randomisation (visit 2). Patients must agree not to receive a live vaccination during the study. No BCG vaccines should be given for one year prior to randomisation (visit 2), during the study and for one year after last administration of study drug (according to the Stelara® SPC).
- History of clinically significant hypersensitivity to a systemically administered biologic agent or its excipients
- History of malignancy in the past 5 years or suspicion of active malignant disease except treated cutaneous squamous cell or basal cell carcinoma
- Has received any therapeutic agent directly targeted to IL 12, IL 23 (including ustekinumab (Stelara®))
- Use of biologic agents within 12 weeks (infliximab, etanercept, adalimumab, other biologics) prior to treatment, systemic anti psoriatic medications or phototherapy within 4 weeks prior to treatment, or topical anti psoriasis medications within 2 weeks prior to treatment

Ages Eligible for Study

18 Years to 75 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

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

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Arm 1 BI 655066 s.c.	Drug: BI 655066 • Low dose
Experimental: Arm 2 BI 655066 s.c.	Drug: BI 655066 • Medium dose
Experimental: Arm 3 BI 655066 s.c.	Drug: BI 655066 • High dose
Active Comparator: Arm 4 Ustekinumab s.c.	Drug: Ustekinumab

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Achievement of ≥90% Reduction From Baseline PASI Score (PASI90) at Week 12	Percentage of participants who achieved ≥90% reduction from baseline in Psoriasis Area and Severity Index score (PASI90) at Week 12. PASI score ranges from 0 (best) to 72 (worst).	Baseline and Week 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Achievement of ≥75% Reduction From Baseline in PASI Score (PASI75) at Weeks 12 and 24	Percentage of participants who achieved ≥75% reduction from baseline in Psoriasis Area and Severity Index score (PASI75) at Weeks 12 and 24. PASI score ranges from 0 (best) to 72 (worst).	Baseline, Week 12 and Week 24
Achievement of 100% Reduction From Baseline in PASI Score (PASI100) at Week 12	Percentage of participants who achieved 100% reduction from baseline in Psoriasis Area and Severity Index score (PASI100) at Week 12. PASI score ranges from 0 (best) to 72 (worst).	Baseline and Week 12
Achievement of ≥50% Reduction From Baseline in PASI Score (PASI50) at Week 12	Percentage of participants who achieved ≥50% reduction from baseline in Psoriasis Area and Severity Index score (PASI50) at Week 12. PASI score ranges from 0 (best) to 72 (worst).	Baseline and Week 12
Achievement of PASI90 at Week 24	Percentage of participants who achieved PASI90 at Week 24. PASI score ranges from 0 (best) to 72 (worst).	Week 24

Percentage Change in PASI Score From Baseline at Week 12	Percentage change in Psoriasis Area and Severity Index (PASI) from baseline at Week 12. PASI score ranges from 0 (best) to 72 (worst).	Baseline and Week 12
Achievement of sPGA Clear or Almost Clear at Week 12	Percentage of participants who achieved static Physician Global Assessment (sPGA) clear or almost clear at Week 12. sPGA is assessed on a six-point scale from 0 (clear) to 5 (severe).	Week 12
Time to Loss of PASI50 Response	Time to loss of PASI50 response.	From first drug administration until end of follow-up period, up to 48 weeks

Collaborators and Investigators

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

Sponsor

Boehringer Ingelheim

Collaborators

No information provided

Investigators

- Study Chair: Boehringer Ingelheim, Boehringer Ingelheim

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
2014-02-03

First Submitted that Met QC Criteria
2014-02-03

First Posted (Estimated)
2014-02-04

Results Reporting Dates

Results First Submitted
2016-07-29

Results First Submitted that Met QC Criteria
2016-07-29

Results First Posted (Estimated)
2016-09-19

Study Record Updates

Last Update Submitted that met QC Criteria
2016-07-29

Last Update Posted (Estimated)
2016-09-19

Last Verified
2016-07

More Information

Terms related to this study

Additional Relevant MeSH Terms

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

Efficacy and Safety of Adalimumab in Subjects With Moderate to Severe Chronic Plaque Psoriasis

ClinicalTrials.gov ID NCT00195676

Sponsor Abbott

Information provided by Abbott

Last Update Posted 2011 04 13

Study Details Tab

Study Overview

Brief Summary

Feedback

The two objectives of this study were to evaluate long term efficacy and safety of adalimumab treatment in participants who had moderate to severe chronic plaque psoriasis and to evaluate the effectiveness of adalimumab retreatment in participants who had therapeutic response to adalimumab and were then withdrawn from adalimumab treatment.

Detailed Description

Study M03 658 was a continuation study for participants with moderate to severe psoriasis who had participated in a prior psoriasis adalimumab study. Study M03 658 consisted of three sequential treatment periods. The first period was Period O, in which participants received open label treatment with adalimumab (40 mg every other week or 40 mg every week) for a minimum of 104 weeks and a maximum of 252 weeks. Period O was the only period of the study until May 2008, when the subsequent periods were added via amendment to the protocol. At that time, participants who had achieved satisfactory therapeutic response (a Physicians Global Assessment [PGA] of 0, 1, or 2 [clear, minimal, or mild]) were given the opportunity to discontinue from the study or to continue and participate in the subsequent two periods. The second period was Period W, a maximum of 52 weeks, in which participants with a PGA of 2 (mild) or less were withdrawn from adalimumab treatment (i.e., participants received no treatment) until relapse of their psoriasis occurred (defined as a PGA of 3 [moderate] or worse). The third period was Period R, a 16 week period in which participants were retreated with open label adalimumab (80 mg initial dose followed by 40 mg every other week). Period O was designed to evaluate the first objective regarding long term efficacy and safety of adalimumab treatment, and Period R was designed to evaluate the effectiveness of adalimumab retreatment following relapse. Specific subsets of the study population that were identified as the populations of interest were the modified intent to treat populations for Period W and Period R, and these are described further in the outcome measures.

Official Title

A Multicenter Open Label Continuation Study in Moderate to Severe Chronic Plaque Psoriasis Subjects Who Completed a Preceding Psoriasis Clinical Study With Adalimumab

Conditions

Psoriasis

Intervention / Treatment

- Drug: adalimumab

Other Study ID Numbers

- M03 658
- 2005 000095 41 (EudraCT Number)

Study Start

2004 05

Primary Completion (Actual)

2009 10

Study Completion (Actual)

2009 10

Enrollment (Actual)

1469

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

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

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

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

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

Contacts and Locations

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

United States

Alabama Locations

Birmingham, Alabama, United States, 35205
Site Reference ID/Investigator# 1263

Buckner 13075 PI, Alabama, United States, 35233
Site Reference ID/Investigator# 1259

Arizona 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:

- Subject was age 18 or older and in good health (Investigator discretion) with a recent stable medical history.
- Subjects who met the requirements from previous adalimumab psoriasis study participation.

Exclusion Criteria:

- Subject considered by the Investigator, for any reason, to be an unsuitable candidate for the study.
- Female subject who was pregnant or breast feeding or considering becoming pregnant.

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
Other: Adalimumab	Drug: adalimumab • 40 mg every other week or 40 mg every week by subcutaneous injection • Other Names: ◦ ABT-D2E7 ◦ Humira

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With a Physicians Global Assessment of Clear or Minimal at Week 16 of Period R	The Physicians Global Assessment [PGA] was scored by the physician using a 6-point scale (0-5) for the degree of overall lesion severity, where 0 = clear, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe, and 5 = very severe. Subjects with a PGA of Clear or Minimal overall lesion severity had scores of 0 or 1.	Week 16 of Period R

Other Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With a Physicians	The Physicians Global Assessment [PGA] was scored by the physician using a 6-point scale (0-5) for the degree of overall lesion severity, where 0 = clear, 1 = minimal, 2 = mild, 3 = moderate, 4 =	Week 60

Global Assessment of Clear or Minimal at Week 60	severe, and 5 = very severe. Subjects with a PGA of Clear or Minimal overall lesion severity had scores of 0 or 1.	
Percentage of Participants With a Physicians Global Assessment of Clear or Minimal at Week 120	The Physicians Global Assessment [PGA] was scored by the physician using a 6-point scale (0-5) for the degree of overall lesion severity, where 0 = clear, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe, and 5 = very severe. Subjects with a PGA of Clear or Minimal overall lesion severity had scores of 0 or 1.	Week 120
Percentage of Participants Who Achieved a Psoriasis Area and Severity Index 75 (PASI 75) Response at Week 60	Psoriasis Area and Severity Index (PASI) scores were calculated from assessments at 4 designated anatomical sites (head, upper extremities, trunk, lower extremities) using both severity and area subscores (i.e., degree of and amount of psoriatic involvement per site). PASI scores range from 0.0 (best) to 72.0 (worst), with the highest score representing complete erythroderma of the severest degree. Positive percent decreases indicate improvement, with the best improvement being 100%. A PASI 75 response was at least a 75% reduction in PASI score from baseline PASI score of the initial study.	Week 60
Percentage of Participants Who Achieved a Psoriasis Area and Severity Index 75 (PASI 75) Response at Week 120	Psoriasis Area and Severity Index (PASI) scores were calculated from assessments at 4 designated anatomical sites (head, upper extremities, trunk, lower extremities) using both severity and area subscores (i.e., degree of and amount of psoriatic involvement per site). PASI scores range from 0.0 (best) to 72.0 (worst), with the highest score representing complete erythroderma of the severest degree. Positive percent decreases indicate improvement, with the best improvement being 100%. A PASI 75	Week 120

	response was at least a 75% reduction in PASI score from baseline PASI score of the initial study.	
Time to Relapse in Period W	Relapse of psoriasis was defined as a Physicians Global Assessment (assessment of overall lesion severity) score of greater than or equal to 3 (3=moderate; 4=severe; 5=very severe).	Period W
Percentage of Period R Modified Intent-to-Treat Participants Who Relapsed in Period W and Subsequently Had a Physicians Global Assessment of Clear or Minimal at Week 16 of Period R	The Physicians Global Assessment [PGA] was scored by the physician using a 6-point scale (0-5) for the degree of overall lesion severity, where 0 = clear, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe, and 5 = very severe. Subjects with a PGA of Clear or Minimal overall lesion severity had scores of 0 or 1.	Week 16 of Period R
Percentage of Period R Modified Intent-to-Treat Participants Who Did Not Relapse in Period W and Subsequently Had a Physicians Global Assessment of Clear or Minimal	The Physicians Global Assessment [PGA] was scored by the physician using a 6-point scale (0-5) for the degree of overall lesion severity, where 0 = clear, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe, and 5 = very severe. Subjects with a PGA of Clear or Minimal overall lesion severity had scores of 0 or 1.	Week 16 of Period R

at Week 16 of Period R		

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, PhD, 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
2005-09-13

First Submitted that Met QC Criteria
2005-09-13

First Posted (Estimated)
2005-09-20

Results Reporting Dates

Results First Submitted
2010-10-20

Results First Submitted that Met QC Criteria
2010-10-20

Results First Posted (Estimated)
2010-11-19

Study Record Updates

Last Update Submitted that met QC Criteria
2011-04-11

Last Update Posted (Estimated)
2011-04-13

Last Verified
2011-04

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

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 Study to Evaluate CNTO 1959 in the Treatment of Patients With Moderate to Severe Plaque-type Psoriasis (X-PLORE)

ClinicalTrials.gov ID NCT01483599

Sponsor Janssen Inc.

Information provided by Janssen Inc. (Responsible Party)

Last Update Posted 2017 08 02

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to evaluate the efficacy and safety of CNTO 1959 in the treatment of patients with moderate to severe plaque psoriasis.

Feedback

Detailed Description

This is a multicenter, dose ranging study of CNTO 1959 in patients with moderate to severe plaque psoriasis. Patients who satisfy all inclusion and exclusion criteria will be assigned by chance to one of 7 treatment groups: a placebo group (a placebo is a treatment identical in appearance to CNTO 1959 but does not contain active drug), 1 of 5 dose groups for CNTO 1959, or adalimumab. Patients assigned to adalimumab will be dosed according to the labeled dosing for psoriasis. At Week 16, patients initially assigned to placebo will begin receiving CNTO 1959. Patients initially assigned to CNTO 1959 will continue to receive the same assigned dose level of study agent from Week 16 through Week 40. Patients receiving adalimumab will continue the labeled dosing regimen. All patients will be reassessed for clinical response every 4 weeks from Week 4 through Week 40. Patients will continue dosing through Week 40, with a subsequent efficacy and safety follow up visit at Week 52. Patient safety will be monitored throughout the study.

Official Title

A Phase 2 Multicenter, Randomized, Placebo and Active Comparator Controlled, Dose Ranging Trial to Evaluate CNTO 1959 for the Treatment of Subjects With Moderate to Severe Plaque type Psoriasis (X PLORE)

Conditions

Psoriasis

Intervention / Treatment

- Drug: CNTO 1959 (5 mg)
- Drug: CNTO 1959 (15 mg)
- Drug: CNTO 1959 (50 mg)
- Drug: CNTO 1959 (100 mg)
- Drug: CNTO 1959 (200 mg)
- Drug: Adalimumab
- Drug: Placebo

Other Study ID Numbers

- CR100673
- CNTO1959PSO2001 (Other Identifier) (OTHER: Janssen Inc.)
- 2011 001066 17 (EudraCT Number)

Study Start (Actual)

2011 11 10

Primary Completion (Actual)

2012 11 27

Study Completion (Actual)

2013 08 05

Enrollment (Actual)

293

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

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

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

Contacts and Locations

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

United States

Alabama Locations

Birmingham, Alabama, United States

California Locations

Bakersfield, California, United States

Click to view interactive map

Los Angeles, California, United States

Santa Monica, 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:

- Diagnosis of plaque type psoriasis with or without psoriatic arthritis for at least 6 months prior to first administration of any study agent
- Must be a candidate for phototherapy or systemic treatment for psoriasis (either new to treatment or having had previous treatment)
- Must be considered, in the opinion of the investigator, suitable candidates for adalimumab therapy
- If a woman, she must be postmenopausal, or if premenopausal, she must be either surgically sterile, practicing a highly effective method of birth control, or not heterosexually active during the study and for 5 months after receiving the last dose of study drug
- If a man, he must agree to use a double barrier method of birth control (or must have been surgically sterilized) and to not donate sperm during the study and for 5 months after receiving the last dose of study drug.

Exclusion Criteria:

- History of or current signs or symptoms of severe, progressive, or uncontrolled renal, hepatic, hematological, gastrointestinal, endocrine, pulmonary, cardiac, neurologic, cerebral, or psychiatric disease
- Has a contra indication to anti TNF therapy
- Has a history of chronic or recurrent infectious disease
- Has a nonplaque form of psoriasis or has drug induced psoriasis
- Has been previously treated with adalimumab
- Has received any therapeutic agent directly targeted to IL 12, IL 17, or IL 23, (including but not limited to ustekinumab, briakinumab [ABT 874], AIN457, and SCH900222) within 6 months of the first administration of study agent.

Ages Eligible for Study

18 Years to 99 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

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

How is the study designed?

Design Details

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

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: CNTO 1959 (5 mg) CNTO 1959 5 mg at weeks 0, 4, and 16, then every 12 weeks through Week 40	Drug: CNTO 1959 (5 mg) • Subcutaneous (SC) injections
Experimental: CNTO 1959 (15 mg) CNTO 1959 15 mg at weeks 0, 8, and 16, then every 8 weeks through Week 40	Drug: CNTO 1959 (15 mg) • SC injections
Experimental: CNTO 1959 (50 mg) CNTO 1959 50 mg at weeks 0, 4, and 16, then every 12 weeks through Week 40	Drug: CNTO 1959 (50 mg) • SC injections
Experimental: CNTO 1959 (100 mg) CNTO 1959 100 mg at weeks 0, 8, and 16, then every 8 weeks through Week 40	Drug: CNTO 1959 (100 mg) • SC injections
Experimental: CNTO 1959 (200 mg)	Drug: CNTO 1959 (200 mg) • SC injections

CNTO 1959 200 mg at weeks 0, 4, and 16, then every 12 weeks through Week 40	
Active Comparator: Adalimumab (approved psoriasis dosing) Adalimumab 80 mg at week 0 followed by 40 mg at week 1 and every second week through Week 39 (i.e., Weeks 3, 5, 7, etc.)	Drug: Adalimumab • SC injections
Placebo Comparator: Placebo to CNTO 1959 (100 mg) Placebo at weeks 0, 4, and 8; then crossover to CNTO 1959 100 mg at Week 16, then every 8 weeks through Week 40	Drug: CNTO 1959 (100 mg) • SC injections Drug: Placebo • SC injections

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With Physician Global Assessment	PGA of psoriasis is used to determine the participant s psoriasis lesions overall at a given time point. Lesions were graded as erythema [0 (no evidence of plaque) to 5 (dusky to deep red coloration)], induration [0 (no plaque evaluation)	Week 16

(PGA) Score of Cleared (0) or Minimal (1) at Week 16	to 5 (marked plaque evaluation)] and scaling [0 (no evidence of scaling) to 5 (severe; very thick tenacious scaling)]. 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= cleared; 1= minimal; 2= mild; 3= moderate; 4= marked and 5= severe).	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants Who Achieved Psoriasis Area and Severity Index (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 percentage (%)-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 could range from 0 (no psoriasis) to 72. PASI 75 response was defined as at least a 75% reduction in PASI relative to Baseline.	Week 16
Difference in Percentage of Participants With Physician Global Assessment (PGA) Score of Cleared (0) or Minimal (1) in CNTO1959 Groups	PGA of psoriasis is used to determine the participant s psoriasis lesions overall at a given time point. Lesions were graded as erythema [0 (no evidence of plaque) to 5 (dusky to deep red coloration)], induration [0 (no plaque evaluation) to 5 (marked plaque evaluation)] and scaling [0 (no evidence of scaling) to 5 (severe; very thick tenacious scaling)]. 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=	Week 16

Compared With Adalimumab Group at Week 16	cleared; 1= minimal; 2= mild; 3= moderate; 4= marked and 5= severe).	
Percentage of Participants With Physician Global Assessment (PGA) Score of Cleared (0) or Minimal (1) at Week 40	PGA of psoriasis is used to determine the participant s psoriasis lesions overall at a given time point. Lesions were graded as erythema [0 (no evidence of plaque) to 5 (dusky to deep red coloration)], induration [0 (no plaque evaluation) to 5 (marked plaque evaluation)] and scaling [0 (no evidence of scaling) to 5 (severe; very thick tenacious scaling)]. 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= cleared; 1= minimal; 2= mild; 3= moderate; 4= marked and 5= severe).	Week 40
Change From Baseline in Dermatology Life Quality Index (DLQI) Score at Week 16	The DLQI is a 10-item questionnaire that measures the impact of skin disease on participant s quality of life. Each question was evaluated on a 4-point scale ranging from 0 (not at all) to 3 (very much); where higher scores indicate more impact on quality of life. The DLQI total score ranges from 0 (not at all) to 30 (very much): 0-1 = no effect at all on the participant s life; 2-6 = small effect on the participant s life; 7-12 = moderate effect on the participant s life; 13-18 = very large effect on the participant s life; 19-30 = extremely large effect on the participant s life. Higher scores indicate more impact on quality of life of participants.	Baseline and Week 16

Collaborators and Investigators

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

Sponsor

Janssen Inc.

Collaborators

No information provided

Investigators

- Study Director: Janssen Inc. Clinical Trial, Janssen 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
2011-11-29

First Submitted that Met QC Criteria
2011-11-29

First Posted (Estimated)
2011-12-01

Results Reporting Dates

Results First Submitted
2017-07-05

Results First Submitted that Met QC Criteria
2017-07-05

Results First Posted
2017-08-02

Study Record Updates

Last Update Submitted that met QC Criteria
2017-07-05

Last Update Posted
2017-08-02

Last Verified
2017-07

More Information

Terms related to this study

Keywords Provided by Janssen Inc.

Moderate to Severe Plaque Type Psoriasis
Psoriasis
Plaque type psoriasis
CNTO 1959
adalimumab

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

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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

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

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

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

TERMINATED

side effect and poor clinical outcome

Addition of Modulators of Homocysteine to Adalimumab Therapy in the Treatment of Moderate to Severe Plaque Psoriasis

ClinicalTrials.gov ID **NCT01704599**

Sponsor Wayne State University

Information provided by Peter J. Aronson, MD, Wayne State University (Responsible Party)

Last Update Posted 2015 02 04

Study Details Tab

Study Overview

Brief Summary

Feedback

Vitamins modulating homocysteine affect both TNF alpha, vascular endothelial growth factor, and theoretically enhance the anti inflammatory version of NOS thus hopefully increasing the efficacy and reducing the chance of some toxicities of adalimumab as determined by blood testing and EKGs.

Detailed Description

This is a pilot study designed to evaluate whether addition of oral vitamin B12, vitamin B6, and folic acid to the use of adalimumab for psoriasis leads to further improvement of a patient s psoriasis and quality of life.

Official Title

A Single Center, Open Label Study to Assess the Effects of the Addition of Modulators of Homocysteine to Adalimumab Therapy in the Treatment of Moderate to Severe Plaque Psoriasis Evaluated With the PASI, PGA and DLQI

Conditions

Psoriasis

Intervention / Treatment

- Drug: Humira Then Humira plus 3 B vitamins

Other Study ID Numbers

- Dermatology 1104009591

Study Start

2009 01

Primary Completion (Actual)

2013 06

Study Completion (Actual)

2014 05

Enrollment (Actual)

8

Study Type

Interventional

Phase

Phase 1
Phase 2

Resource links provided by the National Library of Medicine

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

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

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

Contacts and Locations

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

No location data

Participation Criteria

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

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

Eligibility Criteria

Description

Inclusion Criteria:

- adults 18 or older
- moderate to severe plaque psoriasis (>10% BSA)
- Negative pregnancy test within 7 days before first dose of adalimumab in all women (except surgically sterile or 5 years postmenopausal)
- subject must sign/date appropriate written informed consent&HIPAA authorization
- Sexually active subjects of childbearing potential must agree to use medically acceptable contraception during screening and throughout the study
- no evidence of active or latent tuberculosis based on a negative PPD skin test performed at screening, or within one year of starting this study. Patients with documentation of adequately treated TB may be enrolled
- Patients PPD positive and CXR negative can be enrolled if they finish appropriate INH prophylaxis prior to enrollment
- be willing and able to self administer subcutaneous injections or to have a qualified person available to administer these injections
- agrees to comply with protocol requirements, attend all regularly study visits and is considered to be a good study subject
- meets concomitant medication washout requirements
- willing to use only allowed psoriasis medications and treatments and agree not to start any topical, systemic, or phototherapy for psoriasis during the study period
- adalimumab naïve

Exclusion Criteria:

- erythrodermic, pustular, or guttate psoriasis
- skin conditions other than psoriasis that would interfere with study related psoriasis evaluations
- known sensitivity to any component of the study medications
- Evidence of active infections such as fevers, chills, sweats, or history of untreated Lyme disease and active severe infections within 4 weeks before screening visit, or between the screening and Week 0 visits
- history of listeriosis, untreated TB, persistent or active infections requiring hospitalization or treatment with IV antibiotics, IV antiretrovirals, or IV antifungals within 30 days of baseline, OR oral antibiotics, antivirals, or antifungals for purpose of treating infection, within 14 days of baseline
- positive PPD and positive chest x ray for latent or active tuberculosis
- positive PPD and negative chest x ray that have not completed appropriate INH prophylaxis
- On immune compromising drug or history of immune compromising disorder or immunodeficiency
- poorly controlled medical condition including, not limited to, unstable cardiovascular disease, poorly controlled diabetes, recent stroke, history of recurrent infections, or any

condition for which, in the opinion of the investigators, participation in the study would place the subject at risk
- hx. congestive heart failure
- hx. demyelinating CNS disease
- History of malignancy (other than previously treated localized carcinoma in situ of the cervix or previously treated nonmelanoma skin cancer)
- history of or ongoing drug or alcohol abuse
- past or present psychiatric morbidity which may compromise the study
- Pregnant women, nursing mothers, or planning to become pregnant during study or within 150 days after last dose of study medication. Males planning pregnancy with spouse/partner while in study are to be excluded
- plans to receive any live vaccines during study
- history of liver disease
- Current enrollment in another clinical study/treatment with other experimental drug or approved therapy for experimental use within 30 days prior to Week 0
- previous enrollment in this study
- cannot commit to all assessments required by the protocol
- disorder that compromises the subject to give written informed consent and/or comply with study procedures
- considered by the investigators to be unsuitable candidate
- cannot comply with the protocol washout requirements
- on folic acid in doses over than the minimal daily requirements
- on vitamins higher than minimal daily requirements (multivitamins are allowed)
- colon polyps or cancer
- prior adalimumab therapy
- on screening plasma Vascular Endothelial Growth Factor level is 140 pg/ml or more

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: Humira then Humira plus 3 B vitamins Humira then Humira plus 3 B vitamins The only arm: After 16 weeks on adalimumab, modulators of homocysteine (oral vitamin B12, oral vitamin B6 or pyridoxine, and oral folic acid) will be added to adalimumab therapy for an additional 12 weeks. At end of this therapy can stop or continue. Telephone call day 70 after formal end of in person study the investigators will assess general health of each subject.	Drug: Humira Then Humira plus 3 B vitamins • Humira alone for 16 weeks then Humira plus 100 mg daily pyridoxine, 5 mg daily folic acid and 1000 mcg daily cyanocobalamin • Other Names: ◦ Humira ◦ Adalimumab ◦ Vitamin B6 ◦ Pyridoxine ◦ Vitamin B9 ◦ Folic Acid ◦ Vitamin B12 ◦ Cyanocobalamin

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Particpants With a Categorical PASI (Psoriasis Area and Severity Index) Change	PASI: formula based on body surface areas on head/neck, trunk, both arms & legs with disease quality grading induration, scale and erythema on participants ages 18-65 with moderate to severe plaque psoriasis measured at weeks 16 and 28.	Weeks 16 and 28

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With a Categorical Change in Static Physician Global Assessment (sPGA):	Number of participants with a category change in Physician static Global Assessment (sPGA): 7 point score from 0 (clear) to 6 measuring amount of surface covered and plaque qualities: thickness & erythema plus scaling. Dynamic score compares baseline with either improvement/ worsening of the same factors measured in the sPGA using the 0-6 scoring range but focused on change. sPGA at weeks 16 AND 28. dynamic PGA to be categoically measured at.weeks16 and 28.	Week 16 and Week 28
Number of Participants With a Categorical DLQI (Dermatology	DLQI is 10 questions examining impact of skin disease on quality of life: (1) symptoms & feelings (2) daily activities (3) leisure (4) work & school (5) personal relationship (6) treatment. To be administered to adults over 18 years with moderate to severe plaque psoriasis at week 0 (no systemic psoriasis	Week 16 and Week 28

Life Quality Index) Change	medication);. weeks 16 (after 16 weeks of adalimumab) and week 28 (after 16 weeks adalimumab then 12 weeks of adalimumab plus daily 5 mg folic acid, 100 mg vitamin B6 and 1000 mcg B12).	
Number of Participants With Category Change in Serum VEGF (Vascular Endothelial Growth Factorl)	Adult particpants ages 18 or older with moderate to severe plaque psoriasis were to have serum VEGF measured at week 0 on no systemic psoriasis medication then at both weeks 16 on adalimumab and at week 28 on adalimumab plus folic acid, B6 and Vitamin B12. Subjects raniked by BMI week 0 low to high	At Screening visit, Week 16 on Humira, after another 12 weeks on Humira plus vitamins and if early termination
Number of Participants Within the Categories of Increasing and Decreasing Serum Homocysteine	Serum homocysteine measured at week 16 after 16 weeks of adalimumab and week 28 after 16 weeks of adalimumaband then 12 weeks of adalimumab plus 5 mg folic acid, 100mg B6 and 1000 mcg of B12 in adults ages 18-65 with moderate to sever plaque psoriasis..	Week 16 and Week 28
Number of Participants With Category Change in Vitamin B12 Blood Level	Adult participants 18 years or older with moderate to severe plaque psoriasis were to have serum B12 levels measures Weeks 0 (on no systemic psoriasis medication), 16 (on adalimumab) and week 28 (on adalimumab plus daily 5 mg folic acid, 100 mg vitamin B6 and 1000 mcg B12.	At Week 16 and Week 28

Number of Participants Within the Categories of Increasing and Decreasing Serum Vitamin B6 Level	Serum vitamin B6 levels were to be measured weeks16 after 16 weeks adalimumab and at week 28 after 16 weeks adalimumab and 12 weeks on adalimuamb, folic acid 5 mg, b6 100 mg and B12 1000 mcg in adult participants with moderate to sever plque psoriasis.	At Week 16 and Week 28
Number of Participants With Category Change in Serum Folic Acid Level.	Serum folic acid level in adults ages 18 and older with mild to moderate plaque psoriasis measured at week 16 after 16 weeks adalimumab and at week 28 after 16 weeks adalimumab plus 12 weeks of adalimumab and daily 5 mg folic acid, 100 mg vitamin B6 and 1000 mcg B12.	Weeks 16 and 28

Other Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants in the Categories of Having and Not Having an Adverse Event	Worsening psoriasis or development or worsening of measured condition or new pathology not seen by week 16 but developed at weeks 28 or first discoved by telephone call day 70 post study: AE Humira only	After Week 16 of study
Number of Participants in the Categories of Having and of Not Having a Serious Adverse Event (SAE)	A serious adverse event is hosptalization or death or pathology leading to early termination of a participant from the study. This was to be reported at anytime during the 28 week study of adult patients ages 18-65 with moderate to severe plaque psoriasis though categorized by Week 16 (on adalimumab	By Week 16, by Week 28 and by Day 70 post Week 28.

	alone, by Week 28 (on adalimuamb plus 3 B vitaminsand by day 70 post Week 28.	
Number of Participants in the Categories of Normalizing, Unchanging and Newly Abnormal Electrocardiograms (EKGs)	An electrocardiogram (EKG) is used to evaluate the electrical activity of the heart by converting this activity into line tracings on paper.. Electrodes (small, plastic patches) are placed at certain locations on the chest, arms, and legs. When the electrodes are connected to an EKG machine by lead wires, the electrical activity of the heart is measured, interpreted, and printed out for the doctor s information and further interpretation. This test was to be administered to adults age 18 or older with moderate to severe plaque psoriasis patients at week 0, 16 and week 28 of this study.	Week 16 and then Week 28 after another 12 weeks on Humira plus vitamins and if early termination
Number of Participants in Categories or Increasing and Decreasing Changes Within the CBC (Complete Blood Count)	Change in CBC parameter: white blood count or hemoglobin or hematocrit (as measured week 16 on adalimumab and at week 28 after 12 more weeks on adalimuamb , folic acid, B6 and B12) in adults ages 18-65 with moderate to severe plaque psoriasis.	Week 16 and Week 28
Number of Participants Within the Categories of Increasing and Decreasing Serum Magnesium	Serum magnesium (Mg) was to be measured at baseline, Week 16 (on adalimumab) and at week 28 (on adalimumab plus folic acid, vitamins B6 and B12) in adult participants age 18 or older with moderate to severe plaque psoriasis.	Weeks 16 and 28

Number of Participants Within the Categories of Increasing and Decreasing Serum Phosphorus	Serum phosphorus (P) levels were to be measured weeks16 and 28 in adult participants age 18 and older with moderate to severe plaque psoriasis at week 0 on no systemic psoriasis medication; week 16 after 16 weeks of adalimumab and at week 28 after 16 weeks of adalimumab plus 12 weeks of adalimumab plus 5 mg folic acid, 100 mg vitamin B6 and 1000 mcg of B12.	Week 16 then Week 28
Number of Participants Within the Categories of Elevated and Normal Helicobacter Pylori Antibody	Adult participants age 18 years or older with moderate to severe plaque psoriasis with serum IgG antibodies against Helicobacter pylori bacteria using commercial ELISA assay during the 28 week study.	Week 28 after 16 weeks of Adalimumab then 12 of Adalimumab-Vitamins
Number of Participants Within the Categories of Positive Urine Pregnancy Test (Urine Hcg)	Women of childbearing years over age 18 with moderate to severe plaque psoriasis on no systemic therapy at week 0 of study.	At screening
Number of Participants Within the Categories of Increasing and Decreasing Blood Pressure and Pulse Measures:	Blood pressure is the force the heart exerts against the walls of arteries as it pumps the blood out to the body. The unit of measurement is millimeters of mercury (mm Hg). Pulse is the number of times your heart beats per minute. The unit of measurement is beats per minute (BPM). These test measurements compared in adults with moderate to severe plaque psoriasis week 16 after 16 weeks adalimumab and week 28 after 16 weeks adalimumab plus 5 mg folic acid,	Week 16 and Week 28

	100 mg vitamin B6 and 1000 mcg vitamin B12.	
Number of Participants Within Categories of Body Temperature Change	Using a thermometer for body temperature on degrees Fahrenheit. Participants to be measured were adults 18 years or older with moderate to severe plaque psoriasis with temperature to be measured at week 16 16 weeks of adalimumab and week 28 after 16 weeks of adalimumab then 12 weeks of adalimumab plus 5 mg folic acid, 100 mg vitamin B6 and 1000 mcg of B12.	Weeks 16 and 28
Number of Participants Who Fulfilled the Category of Having Height Measured	Height is the distance from the bottom (soles of feet) to the top (top of head) of a person when that person is standing in this study using ruler in inches.Participants measured were adults age 18 or older with moderate to severe plaque psoriasis.	Week 0 at Start of Adalimumab
Number of Participants Within the Categories of Increasign and Decreasing Body Weight	Weight is how heavy a participant is. Weight in pounds of each study adult participant age 18-65 years with moderate to severe plaque psoriasis measured at weeks 16 and compared to week 28 of study.	Week 16 and Week 28

Collaborators and Investigators

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

Sponsor

Wayne State University

Collaborators

- Abbott

Investigators

- Principal Investigator: Peter J Aronson, MD, Department Dermatology Wayne State University

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

- Aronson PJ, Malick F. Towards rational treatment of severe psoriasis in alcoholics: report of two cases. J Drugs Dermatol. 2010 Apr;9(4):405 8. (https://pubmed.ncbi.nlm.nih.gov/20514802)
- Moat SJ, Madhavan A, Taylor SY, Payne N, Allen RH, Stabler SP, Goodfellow J, McDowell IF, Lewis MJ, Lang D. High but not low dose folic acid improves endothelial function in coronary artery disease. Eur J Clin Invest. 2006 Dec;36(12):850 9. doi: 10.1111/j.1365 2362.2006.01739.x. (https://pubmed.ncbi.nlm.nih.gov/17087779)
- Li W, Zheng T, Wang J, Altura BT, Altura BM. Extracellular magnesium regulates effects of vitamin B6, B12 and folate on homocysteinemia induced depletion of intracellular free magnesium ions in canine cerebral vascular smooth muscle cells: possible relationship to [Ca2+]i, atherogenesis and stroke. Neurosci Lett. 1999 Oct 22;274(2):83 6. doi: 10.1016/s0304 3940(99)00683 7. (https://pubmed.ncbi.nlm.nih.gov/10553943)
- Lewis V, Finlay AY. 10 years experience of the Dermatology Life Quality Index (DLQI). J Investig Dermatol Symp Proc. 2004 Mar;9(2):169 80. doi: 10.1111/j.1087 0024.2004.09113.x. No abstract available. (https://pubmed.ncbi.nlm.nih.gov/15083785)
- Gordon KB, Langley RG, Leonardi C, Toth D, Menter MA, Kang S, Heffernan M, Miller B, Hamlin R, Lim L, Zhong J, Hoffman R, Okun MM. Clinical response to adalimumab treatment in patients with moderate to severe psoriasis: double blind, randomized controlled trial and open label extension study. J Am Acad Dermatol. 2006 Oct;55(4):598 606. doi: 10.1016/j.jaad.2006.05.027. Epub 2006 Aug 10. (https://pubmed.ncbi.nlm.nih.gov/17010738)
- Genovese MC, Mease PJ, Thomson GT, Kivitz AJ, Perdok RJ, Weinberg MA, (https://p

*** 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
2012-10-03

First Submitted that Met QC Criteria
2012-10-09

First Posted (Estimated)
2012-10-11

Results Reporting Dates

Results First Submitted
2014-12-08

Results First Submitted that Met QC Criteria
2015-01-30

Results First Posted (Estimated)
2015-02-04

Study Record Updates

Last Update Submitted that met QC Criteria
2015-01-30

Last Update Posted (Estimated)
2015-02-04

Last Verified
2015-01

More Information

Terms related to this study

Keywords Provided by Peter J. Aronson, MD, Wayne State University

Psoriasis
Adalimumab
B vitamins
Homocysteine
Folic acid
Cyanocobalamin
Pyridoxine
Vitamin B6
Vitamin B9
Vitamin B12

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Micronutrients
Physiological Effects of Drugs
Tumor Necrosis Factor Inhibitors
Anti Inflammatory Agents
Antirheumatic Agents
Hematinics
Vitamins
Folic Acid
Vitamin B 12
Pyridoxine
Vitamin B 6
Vitamin B Complex
Adalimumab

Drug and device information, study documents, and helpful links

Study Documents

No study documents available

Helpful Links Provided by Peter J. Aronson, MD, Wayne State University

Search for Humira (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails)

hypermagnesemia (http://www.emedicine.com/med/topic3383.htm)

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

Safety and Efficacy Study of Combination Treatment With Excimer Laser, Clobex Spray, and Vectical Ointment in the Treatment of Psoriasis

ClinicalTrials.gov ID NCT01012713

Sponsor University of California, San Francisco

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

Last Update Posted 2015 06 18

Study Details Tab

Study Overview

Brief Summary

This is a 12 week, open label, pilot trial evaluating the efficacy and safety of the combination of Clobex® spray with excimer laser therapy as the initial treatment of generalized plaque psoriasis, followed by maintenance therapy with topical Vectical. The study will be conducted in three distinct

Feedback

periods, namely Period A, Period B, and Period C, each of 4 weeks duration. During Period A (weeks 1 through 4), patients will use Clobex® spray twice daily along with excimer laser treatments twice weekly with the Photomedex XTRAC® Velocity machine. The goal of Period A is to achieve Psoriasis Area Severity Index (PASI) 75 in 100% of patients within four weeks. During Period B (weeks 5 through 8), patients would be treated with topical Vectical® twice daily. Thus, there is a steroid free interval during which patients will not be using Clobex® spray. The goal of Period B is to maintain the patient s response using only non steroid options. During Period C of the study, patients will use Clobex® spray BID and Vectical® BID. Period C (weeks 9 through 12) will be a "booster" period in which the goal is to see if 100% of patients can achieve Psoriasis Area Severity Index (PASI) 90 100. Regarding excimer laser therapy: all patients will be receiving excimer laser therapy twice weekly for the first 6 weeks of the study (up to the halfway point) which is 12 excimer laser treatments. At that point, only those patients achieving <Psoriasis Area Severity Index (PASI)75 response will continue to receive twice weekly excimer aser treatments for the remaining 6 weeks of the study.

Detailed Description

Psoriasis is an inflammatory skin disease affecting approximately 2% of the population, and approximately one third of patients experience generalized psoriasis ( ). Current treatment options include topical medications, ultraviolet B and oral psoralen with ultraviolet A phototherapy, biologic agents, non biologic systemic medications, and combinations of the aforementioned. Phototherapy treatment, although effective for many patients, often is inconvenient, requiring three treatments weekly for 2 3 months in order to achieve significant improvement in a patient s psoriasis. The newer biologic medications, while effective in many patients, work by systemic immunosuppression with increased risk of malignancies, infections including tuberculosis and histoplasmosis, congestive heart failure, lupus like syndrome, demyelinating diseases, etc. In addition to side effects from systemic immunosuppression, non biologic systemic agents can have major organ toxicity as a potential side effect including bone marrow suppression, liver toxicity, kidney toxicity, etc.

Currently, we are at the threshold of a new era, where the possibility exists of treating generalized psoriasis with absolute systemic safety and better efficacy than any systemic or biologic agent. This possibility can only become a reality with a "perfect storm," in which three storms collide. This "perfect storm" may achieve a result which no other therapy has yet achieved: a Psoriasis Area Severity Index (PASI)75 response in 100% of patients after only 4 weeks of therapy. The three "storms" include Clobex® spray, Vectical® ointment, and the excimer laser machine XTRAC® Velocity.

Laser therapy (fiberoptically directed monochromatic UVB light) targets only psoriatic plaques. This allows much more aggressive phototherapy as compared to traditional ultraviolet B and oral psoralen with ultraviolet A , which exposes non involved skin as well as psoriatic skin to UV light. With aggressive excimer laser therapy, it is well known that psoriasis can improve significantly or clear in approximately ten sessions instead of the 30 to 40 sessions needed with regular full body phototherapy to achieve clearance of the skin. This dramatic difference is attributed to the fact that psoriatic lesions are able to withstand a much higher dose of light than non involved skin. Excimer laser therapy dosing is determined by the maximum tolerance of psoriatic skin whereas full body UV therapy dosing is determined by the MED (minimal erythema dose) of non involved skin. Delivery of higher doses subsequently results in faster clinical response and much greater clinical efficacy. Hence, the new supra erythemogenic phototherapy strategy results in a fewer number of sessions needed for clearance ( ). The supra erythemogenic phototherapy strategy involves delivering UVB at

a dose much greater than the minimal erythema dose (MED) (2). MED is the traditional limit on how aggressively non laser phototherapy can be conducted (UVB doses beyond the MED will burn the patient).

In addition, excimer laser therapy results in no photo damage to non involved skin, given its targeted application. The Photomedex XTRAC® Velocity is the latest version of the excimer laser, which is 300 400% more powerful than its predecessor, the XTRAC® Ultra machine. This increased power makes treatment of generalized, moderate to severe psoriasis not only feasible but attractive. Time required for each treatment is decreased by one third, as compared to the XTRAC® Ultra which was previously the most powerful excimer laser machine. XTRAC® Velocity is not yet available: it is scheduled to be introduced in a few months. With XTRAC® Velocity, it is expected that generalized psoriasis patients with 10 30% total body surface involvement can be treated in 10 15 minutes and great improvement can be achieved after approximately just ten laser treatment sessions.

Using the XTRAC® Ultra machine, in a pilot study of 9 patients receiving excimer laser therapy twice weekly for 12 weeks, 77% of patients achieved a Psoriasis Area Severity Index (PASI) 75 response ( ). In another study of 124 patients with stable plaque psoriasis (n = 124) covering less than 10% body surface area (BSA) were enrolled and 80 completed the study ( ). Seventy two percent of patients achieved at least 75% clearing in an average of 6.2 treatments. Thirty five percent achieved 90% clearing in an average of 7.5 treatments. In another study of 40 patients treated with the excimer laser under a protocol determined by MED of the involved skin, patients cleared in approximately half the number of treatments compared to patients treated under a protocol where dosage was determined by MED of non involved skin ( ). However, aggressive laser therapy can also irritate the skin, and Clobex® spray can be an ideal partner to enhance the efficacy and prevent irritation of the skin from aggressive, supra erythemogenic UVB irradiation. Moreover, beyond prevention of skin irritation, there are additional merits of combining Clobex® spray with excimer laser. These are the following:

- The very real possibility of synergistic efficacy where two very effective, external therapeutic modalities are combined to possibly result in 100% of patients achieving Psoriasis Area Severity Index (PASI) 75 by not week 12, but week 4 of therapy. If this type of efficacy can be demonstrated, it would wipe out all competition in terms of therapeutic efficacy.
- It is tedious to treat multiple small plaques with excimer laser therapy alone. The use of Clobex® ® spray can help eliminate such small psoriatic plaques en masse.
- Laser therapy can help eliminate stubborn plaques still resistant to Clobex® ® spray used BID for one month.

In a study of 1254 subjects treated with clobetasol propionate spray 0.05% as monotherapy twice daily for four weeks, 35.7% of patients achieved clearance and 37.3% of patients were almost clear using a 6 point target plaque severity scale. Additionally, at week 4, 80% of subjects achieved target plaque severity (TPS) success, $p<0.001$. This was specifically defined as a score of clear, almost clear using the TPS scale or an improvement in severity of 2 grades. Topical steroids have the potential for adrenal suppression. However, when topical steroids are used for one month or less at a time, this transient adrenal suppression that may result is not a clinical problem.Furthermore, when using Clobex® spray, patients are required to have a steroid free interval after 4 weeks of therapy. The effect of Clobex® spray can be maintained with a safe, non steroidal topical medication, such as Vectical. This newer Vitamin D topical agent can be used up to 210 g weekly, as compared to topical calcipotriol (Dovonex®) which is limited to 100 g weekly, due to the better

safety profile of Vectical. Thus, Vectical can be used for patients with generalized plaque psoriasis covering up to 35% body surface area. In addition, a comparative study in 250 patients demonstrated that Vectical caused significantly less skin irritation as compared to calcipotriol ( ). Thus, with the imminent approval of Vectical, we are entering a new era where a Vitamin D analogue can be used to treat patients with generalized psoriasis. With these three "storms" gathering force, we propose the following study.

Official Title

Pilot Open Label Clinical Trial to Test Efficacy and Safety of Combination of Clobex® Spray With Excimer Laser Therapy [Photomedex XTRAC ® Velocity] in the Treatment of Generalized Plaque Psoriasis Followed by Maintenance With Topical Vectical® Ointment

Conditions

Chronic Stable Plaque Psoriasis

Intervention / Treatment

- Drug: Clobex Spray
- Drug: Vectical Ointment
- Procedure: Excimer Laser

Other Study ID Numbers

- Perfect Storm

Study Start

2010 06

Primary Completion (Actual)

2014 12

Study Completion (Actual)

2014 12

Enrollment (Actual)

30

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

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

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

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

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

Contacts and Locations

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

United States

California Locations

San Francisco, California, United States, 94118

UCSF Psoriasis and Skin Treatment Center

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a 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. Male or female subjects 18 years of age of older
2. Subjects should have ≥ 10%, but not more than 20% total body involvement of stable plaque type psoriasis.
3. Subjects must have BMI < 30 and weigh less than 250lbs
4. Subjects must have Fitzpatrick Skin Type II or above (see Attachment A)
5. Subjects must be able to discontinue any topical therapy (other than emollients) or received UVB phototherapy 2 weeks prior to starting the study.
6. Subjects must be able to discontinue any biologic or systemic agents or oral psoralen with ultraviolet A 4 weeks prior to starting the study.
7. Subject is able to complete the study and to comply with study instructions.
8. Subject is capable of understanding and willing to provide signed and dated written voluntary informed consent (and any local or national authorization requirements) before any protocol specific procedures are performed.
9. Any additional diagnoses must, in the investigator s opinion, not preclude the subject from safely participating in this study or interfere with the evaluation of the subject s psoriasis

Exclusion Criteria:

1. Subject is younger than 18 years of age.
2. Subject has less than 10% or greater than 20% body surface involvement of his/her psoriasis.
3. History of known or suspected intolerance to any of the ingredients of the investigational study product.
4. Subject has a photosensitivity disorder (such as lupus, etc.) or a history of clinically significant photosensitivity.
5. Subjects possess other diagnoses that, in the investigator s opinion, preclude him/her from safely participating in this study or interfere with the evaluation of the subject s psoriasis.
6. Subject is not willing to discontinue topical treatment (other than emollients) or UVB phototherapy for 2 weeks prior to starting the study
7. Subject is not willing to discontinue biologic or systemic agents or oral psoralen with ultraviolet A for 4 weeks prior to starting the study.
8. Subject has psoriatic involvement only on the hands, feet, or scalp.
9. Subject has been diagnosed with unstable or non plaque forms of psoriasis, including guttate, erythrodermic, exfoliative, or pustular psoriasis.
10. Subject has a history of keobnerization phenomenon
11. Subject has keloids or past history of keloid formation
12. Subject has melanoma or past history of melanoma
13. Subject has active (cutaneous) invasive non melanoma skin cancer (NMSC)
14. Subject is determined not be a candidate for phototherapy by the investigator
15. Subject has used other investigational drugs within 4 weeks prior to the study

16. Subject is known, or suspected of being unable to comply with the study 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 : Non Randomized
Interventional Model : Single Group Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Open-Label Treatment All patients will receive treatment with Clobex Spray, Vectical Ointment, and Excimer Laser	Drug: Clobex Spray • Clobex Spray BID for Weeks 1-4 and weeks 9-12 Drug: Vectical Ointment • Vectical ointment BID for weeks 5-8 and 9-12 Procedure: Excimer Laser • Laser treatment for weeks 1-6 study and as needed for patients with less than PASI-75 response thereafter.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Primary Endpoint Will be the Percentage of Patients Achieving a 75% Reduction in the Psoriasis Area and Severity Index at Week 12.		12 weeks

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Secondary Endpoint Will be the Percentage of Patients Achieving a 75% Reduction in Psoriasis Area and Severity Index at Weeks 4 and 8.		8 weeks
A Tertiary Endpoint Will be the Percentage of Patients Achieving 90% Reduction in Psoriasis Area and Severity Index at Week 12.		12 weeks

Collaborators and Investigators

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

Sponsor

University of California, San Francisco

Collaborators

No information provided

Investigators

- Principal Investigator: John Koo, MD, UCSF Department of Dermatology

- Study Director: Tina Bhutani, MD, UCSF Department of Dermatology

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
2009-11-10

First Submitted that Met QC Criteria
2009-11-12

First Posted (Estimated)
2009-11-13

Results Reporting Dates

Results First Submitted
2015-05-28

Results First Submitted that Met QC Criteria
2015-06-16

Results First Posted (Estimated)
2015-06-18

Study Record Updates

Last Update Submitted that met QC Criteria
2015-06-16

Last Update Posted (Estimated)
2015-06-18

Last Verified
2015-06

More Information

Terms related to this study

Keywords Provided by University of California, San Francisco

Psoriasis
Excimer
Laser
Clobex
Vectical
clobetasol spray
calcitriol
Generalized plaque type psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Anti Inflammatory Agents
Glucocorticoids
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Physiological Effects of Drugs
Calcium Regulating Hormones and Agents
Calcium Channel Agonists

Membrane Transport Modulators
Molecular Mechanisms of Pharmacological Action
Vasoconstrictor Agents
Vitamins
Micronutrients
Bone Density Conservation Agents
Calcitriol
Clobetasol

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

DFD06 Cream vs Clobetasol Propionate Cream, 0.05% Hypothalamic-Pituitary-Adrenal (HPA) Axis Suppression Study in Patients With Moderate to Severe Plaque Psoriasis (HPA axis)

ClinicalTrials.gov ID NCT02131324

Sponsor Promius Pharma, LLC

Information provided by Promius Pharma, LLC (Responsible Party)

Last Update Posted 2018 05 18

Study Details Tab

Study Overview

Brief Summary

Feedback

The purpose of this study is to evaluate the potential of DFD06 cream to suppress the HPA (hypothalamic pituitary adrenal) axis as compared to clobetasol propionate cream, 0.05% cream when applied twice daily for 15 days.

Detailed Description

This was a 15 day, randomized, multicenter, comparator controlled, open label study. Approximately 50 subjects with moderate to severe plaque psoriasis were to be randomized to treatment with DFD 06 Cream or clobetasol propionate cream in a 1:1 ratio. Study products were applied twice daily for 15 days to all affected areas on the body excluding face, scalp, groin, axillae, and other intertriginous areas. Subject visits were scheduled at Screening, Baseline (Day 1), Day 8, Day 15, and Day 43 (if needed to confirm recovery). Clinical determinations of disease severity were conducted using the Investigator s Global Assessment (IGA) for overall severity at each visit.

Official Title

A Randomized, Open Label, Study to Assess the Potential for Adrenal Suppression and Systemic Drug Absorption With DFD 06 Cream Versus Clobetasol Propionate Cream, 0.05% in Subjects With Moderate to Severe Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: DFD06 Cream
- Drug: Clobetasol Propionate Cream 0.05%

Other Study ID Numbers

- DFD06 CD 007

Study Start (Actual)

2014 05 08

Primary Completion (Actual)

2016 04

Study Completion (Actual)

2016 08 11

Enrollment (Actual)

50

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

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

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

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

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

Contacts and Locations

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

United States

Arizona Locations

Glendale, Arizona, United States, 85308
Advanced Research Associates

Mesa, Arizona, United States, 85202
Agave Clinical Research, LLC

California Locations

Encino, California, United States, 91436
T. Joseph Raoof, MD, 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:

Subjects must present with a clinical diagnosis of stable (at least 3 months) plaque psoriasis.

Subjects with psoriasis involving 20 to 50% Body Surface Area (BSA), not including the face, scalp, groin, axillae and other intertriginous areas.

Subjects must have an IGA grade of at least 3 (moderate) at the Baseline Visit Subjects whose results from the screening Adrenocorticotropic hormone (ACTH) stimulation test are considered normal (cortisol level >18 ug/dL at 30 minutes post stimulation) and show no other signs of abnormal HPA function or adrenal response

Exclusion Criteria:

Current diagnosis of unstable forms of psoriasis including guttate, erythrodermic, exfoliative or pustular psoriasis.

History of organ transplant requiring immunosuppression, HIV, or other immunocompromised state.

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.

Use within 60 days prior to the baseline Visit of: 1) immunosuppressive drugs (e.g., tacrolimus, pimecrolimus), or 2) systemic antipsoriatic treatment (e.g., methotrexate, cyclosporine, hydroxyurea) Use within 30 days prior to the Baseline Visit of: 1) topical antipsoriatic drugs (salicylic acid, anthralin, coal tar, calcipotriene), 2) psoralen and ultraviolet A (PUVA) therapy, 3) systemic anti inflammatory agents (e.g., mycophenolate mofetil, sulfasalazine, 6 thioguanine), or 4) ultraviolet B (UVB) therapy.

Use within 30 days prior to the Screening Visit of any product containing corticosteroids. Inhaled, intraocular, intranasal, etc. steroids are not allowed.

Subjects who have an abnormal sleep schedule or work at night. Subjects with a known history of acute adrenal crisis, Addison s disease or decreased adrenal output, low pituitary function or pituitary tumors.

Subjects who have a history of an adverse reaction to cosyntropin injection or similar test reagents.

Ages Eligible for Study

18 Years to 90 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 : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Active Comparator: Clobetasol Propionate Cream, 0.05% applied twice a day for 15 days	Drug: Clobetasol Propionate Cream 0.05% • Other Names: ◦ Temovate Cream
Experimental: DFD06 Cream applied twice a day for 15 days	Drug: DFD06 Cream • Other Names: ◦ Clobetasol Propionate 0.025% Cream

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Percentage of Subjects With HPA Axis Suppression.	HPA axis suppression as measured by serum cortisol levels post cosyntropin test (ACTH test)	Day 15

Collaborators and Investigators

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

Sponsor

Promius Pharma, LLC

Collaborators

No information provided

Investigators

- Study Director: Srinivas Sidgiddi, MD, Dr. Reddy s Laboratories, Inc

Publications

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

General Publications

No publications available

*** 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
2014-05-02

First Submitted that Met QC Criteria
2014-05-02

First Posted (Estimated)
2014-05-06

Results Reporting Dates

Results First Submitted
2017-05-11

Results First Submitted that Met QC Criteria
2018-03-20

Results First Posted
2018-04-18

Study Record Updates

Last Update Submitted that met QC Criteria
2018-04-19

Last Update Posted
2018-05-18

Last Verified
2018-04

More Information

Terms related to this study

Keywords Provided by Promius Pharma, LLC

Psoriasis

Additional Relevant MeSH Terms

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

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

Yes

Studies A U.S. FDA-Regulated Device Product

No

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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

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

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

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

COMPLETED

Efficacy of Atorvastatin as Adjunctive Treatment for Chronic Plaque Type Psoriasis

ClinicalTrials.gov ID **NCT02432040**

Sponsor Philippine Dermatological Society

Information provided by Sharlene Chua, Philippine Dermatological Society (Responsible Party)

Last Update Posted 2015 11 23

Study Details Tab

Study Overview

Brief Summary

This study aimed to assess the efficacy and safety of atorvastatin 40 mg/day as an adjunct to betamethasone valerate 0.1% ointment applied twice daily in the treatment of patients with mild to moderate chronic plaque type psoriasis, as determined by mean reduction in PASI scores. Specific

Feedback

objectives included the determination and comparison of the absolute number and proportion of patients who achieved PASI 50 and the mean reductions in lipid profile (total cholesterol, HDL, LDL, triglycerides) and high sensitivity C reactive protein (hsCRP) measured from baseline and every month thereafter up to 6 months of treatment. This study also investigated the impact of atorvastatin treatment on the patients quality of life as well as the association of clinical response to the lipid lowering and anti inflammatory effects of atorvastatin.

Detailed Description

This was a single center, parallel group, randomized, double blind, placebo controlled clinical trial. The study was conducted from February 2013 to October 2013 at a dermatology out patient clinic in a tertiary hospital in the Philippines. Twenty eight patients aged 19 65 years old assessed to have mild to moderate chronic plaque psoriasis, with psoriasis area and severity index (PASI) scores less than 10, were enrolled into the study and randomized into two equal treatment groups. Before participating in the study, patients were required to have a washout period of psoriasis pharmacotherapy for at least 2 months for phototherapy and systemic drugs, and 2 weeks for topical therapies.

Exclusion criteria were as follows: patients with uncontrolled hypertension, endocrine or other metabolic diseases; patients with known allergy to any of the treatments; patients with active liver disease or liver enzymes (AST and ALT) thrice the upper limit; patients with any myopathy or presence of elevated creatine kinase (CK MM) levels; patients taking any drug that might interact with statins and those already taking statins or patients with clear indications for statin treatment; patients with impaired renal function or creatinine > 2.0 mg/dL; patients with active infection or white blood cell (WBC) > 10 and pregnant or lactating females. The study was conducted in accordance with the Declaration of Helsinki and approved by the ethics committee. Informed consent was obtained from all participants at study entry.

Patients were randomly assigned into the two groups through a computer generated randomization table with sequencing of assignments unknown to the primary investigator. The assigned interventions were placed in sequentially numbered, opaque envelopes, which were opened by one of the secondary investigators only after the patient had agreed to participate in the study. Patients were assigned numerical codes that were indicated in their case record forms.

Fourteen patients took atorvastatin 40 mg once a day while 14 patients took a similar looking placebo tablet once a day. The study duration was 6 months. All patients were allowed to continue the use of betamethasone valerate 0.1% ointment twice a day for the duration of the study. Dispensing of the medications was done by a secondary investigator, while clinical assessment was done by the primary investigator who was blinded to the treatment assignments.

Patients PASI scores, lipid profiles, aspartate aminotransferase (AST), alanine aminotransferase (ALT), hsCRP levels, and dermatology life and quality index (DLQI) scores were taken at baseline. Recording of the lipid profile, and AST, ALT values was done by another secondary investigator so that the primary investigator would not be biased by the decreasing values of the lipid profile or elevations in the AST or ALT. Photo documentation was done throughout the study. Patients were also asked to bring their medications each visit so that the primary investigator could check for compliance. PASI scores, lipid profiles, AST, and ALT levels were monitored monthly, while DLQI scores and hsCRP levels were evaluated again after 6 months of therapy. Difference in the mean changes in PASI scores, lipid profile levels, DLQI scores, and hsCRP levels between groups were

compared. Difference in the proportion of patients reaching 50% reduction in PASI scores (PASI 50) after 3 months and that after 6 months of therapy were compared. Correlation between the changes in PASI scores and the changes in lipid profile levels, as well as correlation between the changes in PASI scores and the changes in hsCRP levels were computed.

The period of observation for adverse events started from the time the subject received the first dose of the study drug until his last follow up. Adverse event monitoring was by active query and spontaneous reporting.

Intention to treat analysis was the primary efficacy analysis. Patients included were those who had at least one assessment beyond baseline (Month 1). The last measurement of each randomized patient was moved forward to represent the end of treatment measurement at 6 months. Per protocol analysis was the secondary efficacy analysis. All data analyses were performed using a statistical software (STATA 12.0).

Official Title

Atorvastatin as Adjunctive Therapy for Chronic Plaque Type Psoriasis Versus Betamethasone Valerate Alone:A Randomized, Double Blind, Placebo Controlled Trial

Conditions

Psoriasis

Intervention / Treatment

- Drug: Atorvastatin
- Drug: Placebo

Other Study ID Numbers

- PDS_PGH_2013_002

Study Start

2013 02

Primary Completion (Actual)

2013 10

Study Completion (Actual)

2013 11

Enrollment (Actual)

28

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

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.

Philippines

Manila, Philippines, 1000
University of the Philippines - Philippine General Hospital Section of 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 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 diagnosed with mild to moderate psoriasis vulgaris, chronic plaque type, with PASI score not more than 10
- Adult patients ≥ 19 years old and ≤ 65 years old
- Male or female
- Able to give consent
- Able to follow up monthly for 6 months

Exclusion Criteria:

- Patients with PASI score ≥ 10
- Systemic therapy for psoriasis within the last two months
- Phototherapy within the last four weeks
- Known allergy to any of the treatments
- Active liver disease or liver enzymes (AST and ALT) more than 3 times the upper limit of normal
- Any myopathy or presence of elevated creatine kinase (CK MM) levels
- Intake of any drug that might affect or interact with the study drug (e.g. fibrates, niacin, macrolide antibiotics)
- Patients already taking statins or patients with clear indications for statin treatment (i.e. coronary heart disease or disease equivalents according to the Adult Treatment Panel III Guidelines)
- Impaired renal function or creatinine > 2.0 mg/dL
- Active infection or WBC > 10
- Pregnant or lactating
- Uncontrolled hypertension, endocrine or other metabolic diseases

Ages Eligible for Study

19 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 : Triple (Participant, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Atorvastatin Atorvastatin 40 mg once a day at night Patients asked to apply Betamethasone valerate 0.1% ointment twice a day, 3 weeks on, 1 week off, at the most	Drug: Atorvastatin • Atorvastatin is a hydroxymethylglutaryl-coenzyme A (HMG-CoA) reductase inhibitor used to treat dyslipidemia • Other Names: ◦ Atopitar
Placebo Comparator: Placebo Placebo tablets But patients are still asked to apply Betamethasone valerate 0.1% ointment twice a day, 3 weeks on, 1 week off, at the most	Drug: Placebo • Placebo tablets, made to look like the interventional drug

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Mean Gross Change in Psoriasis Area and Severity Index (PASI) Scores From Baseline to the End of 6 Months	Psoriasis Area and Severity Index involves grading psoriatic plaques based on erythema (E), infiltration (I), desquamation (D). Severity is graded from 0-4 for each criteria (0 - none, 1 - slight, 2 - moderate, 3 - severe, and 4 - very severe). The body is divided into 4 regions, head, upper extremities, trunk, and lower extremities, and for each region, the surface area involvement is graded on a 0-6 scale (0 - 0% involvement, 1 - <10%, 2 - 10-<30%, 3 - 30-<50%, 4 - 50-<70%, 5 - 70-<90%, 6 - 90-100%).The highest potential PASI score is 72, with higher PASI scores indicating worse psoriasis.	6 months
Percentage of Patients Achieving PASI-50 in Each Arm at the End of 6 Months	Percentage of patients in each arm who will achieve 50% reduction in PASI scores at the end of 6 months will be compared	6 months

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Monthly Mean Changes in PASI Scores	PASI scores were measured monthly and mean changes from baseline for each month for the whole 6-month duration of the study recorded.	Monthly from baseline to 6 months

Percentage of Patients Achieving PASI-50 at the End of 3 Months	PASI-50 means at least a 50% reduction from baseline PASI score	3 months
Mean Change in Dermatology Life Quality Index (DLQI) Scores After 6 Months		6 months
Mean Change in Lipid Profile Levels		6 months
Mean Change in hsCRP Levels		6 months
Adverse Events		6 months

Collaborators and Investigators

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

Sponsor

Philippine Dermatological Society

Collaborators

No information provided

Investigators

- Principal Investigator: Sharlene H Chua, Medicine, University of the Philippines Philippine General Hospital Section of Dermatology

- Study Director: Ma. Lorna F Frez, Medicine, University of the Philippines Philippine General Hospital Section of Dermatology

Publications

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

General Publications

No publications available

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

Study Record Dates

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

Study Registration Dates

First Submitted
2015-04-28

First Submitted that Met QC Criteria
2015-04-28

First Posted (Estimated)
2015-05-01

Results Reporting Dates

Results First Submitted
2015-05-02

Results First Submitted that Met QC Criteria
2015-10-21

Results First Posted (Estimated)
2015-11-23

Study Record Updates

Last Update Submitted that met QC Criteria
2015-10-21

Last Update Posted (Estimated)
2015-11-23

Last Verified
2015-10

More Information

Terms related to this study

Keywords Provided by Sharlene Chua, Philippine Dermatological Society

chronic plaque psoriasis
psoriasis
atorvastatin
psoriasis area and severity index
betamethasone valerate

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Anticholesteremic Agents
Hypolipidemic Agents
Antimetabolites
Molecular Mechanisms of Pharmacological Action
Lipid Regulating Agents
Hydroxymethylglutaryl CoA Reductase Inhibitors
Enzyme Inhibitors
Atorvastatin

Study Documents

No study documents available

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

Combining Topical Corticosteroid and LCD Treatment for Localized Plaque Psoriasis

ClinicalTrials.gov ID NCT00769184

Sponsor NeoStrata Company, Inc.

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

Last Update Posted 2015 08 19

Study Details Tab

Study Overview

Brief Summary

Feedback

This is a 12 week bilateral study, consisting of 6 weeks of treatment and 6 weeks of follow up. The purpose of the study is to compare the safety and effectiveness of combining and then following a high potency topical corticosteroid treatment with LCD treatment for moderate to severe localized plaque psoriasis.

Detailed Description

Superpotent topical corticosteroids such as clobetasol propionate are highly effective in treating plaque psoriasis but are not indicated for long term use due to their side effects. Therefore, steroid sparing combination and sequential regimens, in which the corticosteroid gets supplemented with a non steroid medication, such as calcipotriol or tazarotene, have become the standard of care, especially in the management of localized psoriasis lesions. A new steroid free 15% liquor carbonis distillate (LCD) solution (Psorent) was recently found to be more successful than 0.005% calcipotriol cream (Dovonex) at improving and delaying worsening of psoriasis symptoms in a controlled clinical trial. The goal of this pilot study is to evaluate if this LCD solution can be used in combination with acute topical corticosteroid therapy as a new steroid sparing / enhancing regimen. We hope to explore the compatibility, patient tolerability, and clinical benefit of using LCD solution during and after treatment with clobetasol propionate in adults with moderate to severe plaque psoriasis. This is a randomized, double blind, vehicle controlled, bilateral study. Men and women 18 years of age or older, with chronic plaque psoriasis affecting less than or equal to 10% body surface area (BSA) in areas other than the scalp, face, palms, soles, axillae, and groin, are recruited. Those with a Physician Global Assessment (PGA) score greater than 3 and are in general good health will qualify as candidates. On one side of the body, LCD solution and clobetasol propionate will be administered twice daily for the first 2 weeks of treatment, followed by 4 weeks of LCD solution only, followed by 6 weeks of no treatment. On the second half of the body, subject will apply a vehicle solution and clobetasol propionate twice daily for the first 2 weeks, only the vehicle solution twice daily for the next four weeks, and then no treatment for the next 6 weeks. Subjects will be evaluated at weeks 2, 4, 6, 8, 10 and 12. investigators will use the PGA scale [Clear (0) Severe (5)] to determine treatment effects as well as Target Lesion assessments of Erythema, Scaling, Induration and overall severity [None (0) Very Severe (4)]. patients will also be required to complete Self Assessment questionnaires on their psoriasis [None (0) Severe (6)]. as well as an assessment of the study solution [Excellent (9) Poor (1)]. . Photographs will be taken at each study visit and adverse events will be monitored throughout the study.

Official Title

A Steroid Sparing Effect of Supplemental LCD Treatment in Patients With Moderate to Severe Localized Psoriasis Lesions: a Pilot Study.

Conditions

Psoriasis

Intervention / Treatment

- Drug: Corticosteroid
- Other: Placebo

- Drug: LCD

Other Study ID Numbers

- 08 LCDSTRD

Study Start

2008 10

Primary Completion (Actual)

2009 04

Study Completion (Actual)

2009 04

Enrollment (Actual)

15

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) Steroids (https://medlineplus.gov/steroids.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

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 of age or older
- able to provide written informed consent
- able to attend study visits, apply medications, and follow instructions
- moderate to severe localized plaque psoriasis lesions (<10% BSA on each side of the body)

Exclusion Criteria:

- other current treatments for psoriasis
- hypersensitivity to steroids, liquor carbonis detergens, alcohol, fragrance
- pregnant or nursing

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

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Corticosteroid + LCD corticosteroid and LCD treatment (2 weeks), LCD alone treatment (4 weeks)	Drug: Corticosteroid • One side of body: clobetasol: 2 applications / day along with LCD application 2 applications/day • Other Names: ◦ clobetasol Drug: LCD • One side of body: LCD Solution: 2 applications / day along with clobetasol 2 applications/day • Other Names: ◦ liquor carbonis distillate
Placebo Comparator: Corticosteroid + Placebo corticosteroid and placebo treatment (2 weeks), placebo alone treatment (4 weeks)	Drug: Corticosteroid • One side of body: clobetasol: 2 applications / day along with LCD application 2 applications/day • Other Names: ◦ clobetasol Other: Placebo • One side of body: Placebo Solution: 2 applications / day along with clobetasol 2 applications/day

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Patients Who Are Clear (PGA Score 0) or Have Minimal Disease (PGA Score 1) on Each Treated Side at Each Visit.	Those patients that have reached a PGA score of zero [PGA scale: clear (0) - very severe (5)], and are considered clear of chronic plaque psoriasis, or have reached a PGA score of 1, with minimal disease at each visit, in each condition. Data was collected at weeks 2, 6 and 12.	Weeks 2, 6, & 12.

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Mean Percent Improvement in Disease Severity Using PGA and OTLS Scores of Target Lesions	Mean percent improvement in disease severity using Physician Global Assessment (PGA) [PGA scale: Clear (0) - Very Severe (5)] and overall severity scores of target lesions (OTLS) [OTLS scale None (0) - Very Severe (4)] based on erythema, scaling and induration, at each visit interval.	Weeks 2, 6, & 12

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, Psoriasis Treatment Center of Central New Jersey

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
2008-10-07

First Submitted that Met QC Criteria
2008-10-08

First Posted (Estimated)
2008-10-09

Results Reporting Dates

Results First Submitted
2014-11-14

Results First Submitted that Met QC Criteria
2015-07-22

Results First Posted (Estimated)

2015-08-19

Study Record Updates

Last Update Submitted that met QC Criteria

2015-07-22

Last Update Posted (Estimated)

2015-08-19

Last Verified

2015-07

More Information

Terms related to this study

Keywords Provided by NeoStrata Company, Inc.

chronic plaque psoriasis

Additional Relevant MeSH Terms

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

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 Phase 3 Trial to Look at the Safety and Effectiveness of Ustekinumab in Korean and Taiwanese Subjects With Moderate to Severe Plaque-type Psoriasis

ClinicalTrials.gov ID NCT00747344

Sponsor Centocor, Inc.

Information provided by Centocor, Inc. (Responsible Party)

Last Update Posted 2013 03 29

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to evaluate the efficacy and safety of Ustekinumab in the treatment of patients with moderate to severe psoriasis in South Korea and Taiwan.

Feedback

Detailed Description

This is phase 3, multicenter, randomized, placebo controlled double blind, parallel study of subcutaneous injection of placebo and ustekinumab 45mg in Taiwanese and Korean patients with moderate to severe plaque psoriasis. Ustekinumab is an experimental medicine that is being tested to see if it may be useful in treating moderate to severe psoriasis. The patients will receive either ustekinumab or placebo at week 0 or week 4, and will be followed up through week 36. Patients who randomized (study drug assigned by chance) to placebo will cross over to ustekinumab 45mg group at week 12 and week 16 .The effectiveness of ustekinumab will be compared with placebo treated patients at week 12. Safety information will be collected through week 36. Patients randomized to ustekinumab will receive placebo at week 12 to maintain the blind and additional dose of 45mg at week 16. This study will be conducted in approximately 13 sites in South Korea and Taiwan and will include approximately 120 patients with approximately 60 patients in each country. This study is "blinded." This means that neither you nor your study doctor will know in which group you are placed. However, in case of medical emergency, your study doctor can quickly find out which treatment group you are in. You may get either ustekinumab or placebo (which looks like the medicine being studied but has no active ingredients) at the start of the study. All patients in the study will eventually receive Ustekinumab after week 12. Patients assigned to the ustekinumab will receive 45 mg subcutaneously at weeks 0, 4 and 16; and placebo at week 12. Patiens assigned to placebo will receive subcutaneous injections of placebo at weeks 0 and 4; then crossover to 45 mg of ustekinumab at weeks 12 and 16. Duration of study participation up to 36 weeks.

Official Title

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

Conditions

Psoriasis

Intervention / Treatment

- Drug: Placebo Controlled Period (CP)
- Drug: Ustekinumab 45 mg CP
- Drug: Placebo to ustekinumab 45 mg after CP
- Drug: Ustekinumab 45 mg after CP

Other Study ID Numbers

- CR015313

Study Start

2008 12

Primary Completion (Actual)

2009 09

Study Completion (Actual)

2010 03

Enrollment (Actual)

121

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.

Korea, Republic of

Anyang, Korea, Republic of

Seoul, Korea, Republic of

Taiwan

Click to view interactive map

- **Changhua, Taiwan**
- **Kaohsiung County, Taiwan**
- **Taipei, Taiwan**

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 be of Taiwanese or Korean ancestry living in Taiwan or South Korea, respectively
- Have a diagnosis of plaque type psoriasis at least 6 months prior to first administration of study agent (patients with concurrent psoriatic arthritis may be enrolled)
- Have plaque type psoriasis covering at least 10% of total body surface area at screening and at the time of first study agent administration
- PASI score of 12 or greater at the time of screening and at time of first study agent administration
- Candidate of phototherapy or systemic treatment of psoriasis (either naïve or history of previous treatment)
- Be able to adhere to the study visit schedule and other protocol requirements
- Capable of giving informed consent prior to any study related procedures.

Exclusion Criteria:

- Currently have a non plaque form of psoriasis
- Have current drug induced psoriasis
- Are pregnant or nursing or planning pregnancy (both men and women) while enrolled in the study
- Have used any investigational drug within the previous 4 weeks or 5 times the half life of the investigational agent, whichever is longer
- Have used any biologic within the previous 3 months or 5 times the half life of the biologic, whichever is longer
- Have been hospitalized in the past 3 years for asthma, ever required intubation for treatment of asthma, currently require oral corticosteroids for the treatment of asthma, or required more than one short term course of oral corticosteroids for asthma within the previous year
- Have a history of latent or active granulomatous infection, including TB, histoplasmosis, or coccidioidomycosis prior to screening.

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 : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Placebo Comparator: Placebo - Controlled Period (CP)	Drug: Placebo - Controlled Period (CP) • Placebo, Weeks 0-12
Experimental: Ustekinumab 45 mg - CP	Drug: Ustekinumab 45 mg - CP • Ustekinumab 45 mg, Weeks 0-12
Experimental: Placebo to ustekinumab 45 mg - after CP	Drug: Placebo to ustekinumab 45 mg - after CP • Placebo at Weeks 0 and 4, then ustekinumab 45 mg at Week 12 and Week 16
Experimental: Ustekinumab 45 mg - after CP	Drug: Ustekinumab 45 mg - after CP • Ustekinumab 45 mg at Weeks 0 and 4, then placebo at Week 12 and ustekinumab 45 mg at Week 16

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Number of Patients Who Achieved at Least a 75% Improvement in PASI (Psoriasis Area and Severity Index) at Week 12	PASI score can range from 0 (no psoriasis) to 72 (severe psoriasis).	Week 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The Number of Patients With a Physicians Global Assessment (PGA) Score of Cleared (0) or Minimal (1) at Week 12		Week 12
The Change in Dermatology Life Quality Index (DLQI) From Baseline at Week 12	Scores could range from 0 to 30. A lower DLQI score represents better quality of life.	Baseline to Week 12

Collaborators and Investigators

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

Sponsor

Centocor, Inc.

Collaborators

No information provided

Investigators

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

Publications

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

General Publications

No publications available

*** 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

2008-09-04

First Submitted that Met QC Criteria

2008-09-04

First Posted (Estimated)
2008-09-05

Results Reporting Dates

Results First Submitted
2012-09-05

Results First Submitted that Met QC Criteria
2012-09-05

Results First Posted (Estimated)
2012-10-05

Study Record Updates

Last Update Submitted that met QC Criteria
2013-03-22

Last Update Posted (Estimated)
2013-03-29

Last Verified
2013-03

More Information

Terms related to this study

Keywords Provided by Centocor, Inc.

Psoriasis
Psoriatic Arthritis
Ustekinumab
CNTO 1275

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Dermatologic Agents

Ustekinumab

Study Documents

No study documents available

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

Desoximetasone Spray 0.05%, 0.25%; Dose Ranging Study

ClinicalTrials.gov ID **NCT01018134**

Sponsor Taro Pharmaceuticals USA

Information provided by Taro Pharmaceuticals USA (Responsible Party)

Last Update Posted 2014 08 05

Study Details Tab

Study Overview

Brief Summary

The objectives of this study are to evaluate the efficacy and safety of two dosing regimens of desoximetasone 0.05% and 0.25% topical sprays as compared to a vehicle spray in patients with moderate to severe plaque psoriasis.

Feedback

Official Title

A Double Blind, Vehicle Controlled, Randomized, Dose Ranging, Multiple Site Clinical Study to Evaluate the Efficacy and Safety of Desoximetasone Topical Sprays (0.05%, 0.25%) in Patients With Moderate to Severe Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Desoximetasone 0.05% once daily
- Drug: Desoximetasone 0.05% twice daily
- Drug: Desoximetasone 0.25% once daily
- Drug: Desoximetasone 0.25% once daily
- Drug: Vehicle once daily
- Drug: Vehicle twice daily

Other Study ID Numbers

- DSXS 0906.00
- 70915004 (Other Identifier) (OTHER: Novum PRS)

Study Start

2009 11

Primary Completion (Actual)

2010 05

Study Completion (Actual)

2010 05

Enrollment (Actual)

151

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

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

Contacts and Locations

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

United States

Florida Locations

Miami, Florida, United States
Investigator Site

Georgia Locations

Martinez, Georgia, United States
Investigator Site

Kansas 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:

- 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:

- Pregnancy
- Current diagnosis of other types of psoriasis other than stable plaque psoriasis or has psoriasis of any kind of the face or scalp that will require active treatment during the study.
- History of psoriasis that has been unresponsive to topical corticosteroid therapy.
- Dermatological conditions that may interfere with the clinical assessments of the signs and symptoms of psoriasis.
- Allergy or sensitivity to corticosteroids or history of any drug hypersensitivity or intolerance which would compromise the safety of the patient or the results of the study.
- Any condition that would place the study patient at undue risk by participation in the study.
- Radiation therapy, antineoplastic agents or immunosuppressant medication within 4 weeks prior to the first dose of study drug.
- Treatment with any systemic or photo antipsoriatic therapy, within 8 weeks of the first dose of study drug.
- Treatment within 12 weeks (or five half lives, whichever is less) prior to the first dose of study drug with any biological therapies for psoriasis.
- 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.
- Hormonal contraceptives for less than one complete cycle prior to entering the study.
- 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 : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Desoximetasone 0.05% once daily Desoximetasone topical spray 0.05% administered once daily to affected area	Drug: Desoximetasone 0.05% once daily • Desoximetasone topical spray 0.05% administered to affected area once daily for 28 days
Experimental: Desoximetasone 0.05% twice daily Desoximetasone topical spray 0.05% administered twice daily to affected area	Drug: Desoximetasone 0.05% twice daily • Desoximetasone topical spray 0.05% administered to affected area twice daily for 28 days
Experimental: Desoximetasone 0.25% once daily Desoximetasone topical spray 0.25% administered once daily to affected area	Drug: Desoximetasone 0.25% once daily • Desoximetasone topical spray 0.25% administered to affected area once daily for 28 days
Experimental: Desoximetasone 0.25% twice daily Desoximetasone topical spray 0.25% administered twice daily to affected area	Drug: Desoximetasone 0.25% once daily • Desoximetasone topical spray 0.25% administered to affected areas twice daily for 28 days

Placebo Comparator: Vehicle once daily Vehicle administered to affected areas once daily	Drug: Vehicle once daily • Vehicle topical spray administered to affected areas once daily for 28 days
Placebo Comparator: Vehicle twice daily Vehicle administered to affected areas twice daily	Drug: Vehicle twice daily • Vehicle topical spray administered to affected areas twice daily for 28 days

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants in Each Treatment Group With Clinical Cure: Physicians Global Assessment (PGA) Score = 0 or 1 at Day 28	The primary endpoint was the proportion of patients in each treatment group who were considered a Clinical Success (PGA score of 0 or 1) at Day 28 for each of the three signs/symptoms (i.e., scaling, erythema and plaque elevation) The primary measure of efficacy was evaluated using those patients eligible for inclusion in the ITT population. On a seven point grade PGA scale a patient will be considered a Clinical Success if: the patients PGA score is 0 or 1. A score of 0 = Clear or 1= Almost Clear was considered clinical success. A patient will be considered a Clinical Failure if: the patients PGA score is > 1, the patient was	28 days

	considered to have an insufficient therapeutic response	
Number of Participants in Each Treatment Group With Treatment Success for the Target Lesion (Total Lesion Severity Scale (TLSS) a Score of 0 or 1).	The proportion of patients in each treatment group who were considered a Treatment Success for the target lesion (a score of 0 or 1 for each of the three signs/symptoms (i.e., scaling, erythema and plaque elevation)) at Day 28. Each component was given a score using the following scale: 0=clear, 1=Almost Clear, 2=Mild, 3=Moderate, 4=Severe, 5=Very Severe., with increasing score reflecting increased lesion severity. The TLS score is calculated as the sum of the 3 components. A TLS score of 0 = Clear or 1= Almost Clear was considered treatment success.	Day 28

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Mean Change From Baseline in PGA Score at Day 28 Using the ITT	Physician Global Assessment (PGA) of Psoriasis is scored based on dermatologist s assessment of disease averaged over all lesions of face, genitals, or intertriginous area (i.e., breast fold, gluteal crease, axilla). Overall lesions were graded for plaque formation, induration, erythema, and scaling; range: 0 (clear) to 5 (very severe). The severity score was summed and averaged after which the total average is 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; 5=very severe). PGA response was	Day 28

	defined as 0 (clear) or 1 (almost clear) Higher scores indicate greater severity of disease.	
Mean Change From Baseline in Total Lesion Severity Score (TLSS) at Day 28	Each lesion was evaluated for 3 components: erythema, plaque elevation, and scaling. Each component was given a score using the following scale: 0=clear, 1=Almost Clear, 2=Mild, 3=Moderate, 4=Severe, 5=Very Severe., with increasing score reflecting increased lesion severity. The TLS score is calculated as the sum of the 3 components.	Day 28
Mean Change From Baseline in %Body Surface Area (%BSA) Affected at Day 28 (or Early Termination).	Body Surface Area (BSA) is a numerical score used to measure the physician s assessment of the percentage of the participant s total BSA involved with psoriasis. BSA = SQRT ((height (cm) X weight (kg))/3600) BSA is in m2, W is weight in kg, and H is height in cm. Total body Surface Area (BSA) in meters squared %Body Surface Area Affected the "Rule of Nine" was be used.	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

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
2009-11-19

First Submitted that Met QC Criteria
2009-11-19

First Posted (Estimated)
2009-11-23

Results Reporting Dates

Results First Submitted
2014-01-31

Results First Submitted that Met QC Criteria
2014-07-09

Results First Posted (Estimated)
2014-08-05

Study Record Updates

Last Update Submitted that met QC Criteria
2014-07-09

Last Update Posted (Estimated)
2014-08-05

Last Verified
2014-07

More Information

Terms related to this study

Keywords Provided by Taro Pharmaceuticals USA

Psoriasis
Topical corticosteroids
Plaque psoriasis

Additional Relevant MeSH Terms

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

Study Documents

No study documents available

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 Plaque Test Comparing the Anti-psoriatic Effect of Marketed Products for Topical Use for Psoriasis Vulgaris

ClinicalTrials.gov ID **NCT00845481**

Sponsor LEO Pharma

Information provided by LEO Pharma (Responsible Party)

Last Update Posted 2015 04 14

Study Details Tab

Study Overview

Brief Summary

The purpose of the study is to compare the anti psoriatic effect of marketed products with Daivobet® ointment in a plaque test

Feedback

Official Title

A Plaque Test Comparing 4 Steroids With Daivobet® Ointment and a Vehicle Control for the Treatment of Psoriasis Vulgaris

Conditions

Psoriasis Vulgaris

Intervention / Treatment

- Drug: Daivobet® ointment
- Drug: Betnovat® ointment
- Drug: Diprosalic ointment
- Drug: Dermovat ointment
- Drug: Elocon ointment
- Drug: Daivobet® ointment vehicle

Other Study ID Numbers

- PLQ 002

Study Start

2009 01

Primary Completion (Actual)

2009 03

Study Completion (Actual)

2009 05

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)

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

St Quentin Yvelines Cedex, France, 78054
LEO Pharma 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: (in summary)

- Subjects having understood and signed an informed consent form
- All skin types
- Subjects with a diagnosis of psoriasis vulgaris with lesions located on arms, legs or trunk. The lesions must have a total size suitable for application. The subjects should be asked if their lesions have been stable
- Subjects willing and able to follow all the study procedures and complete the whole study
- Subjects affiliated to social security system

Exclusion Criteria: (in summary)

- Females who are pregnant, of child bearing potential and who wish to become pregnant during the study, or who are breast feeding
- Subjects using biological therapies (marketed or not marketed) with a possible effect on psoriasis (e.g. alefacept, efalizumab, etanercept, infliximab, adalimumab) within 12 weeks prior to study drug administration
- Systemic treatments with all other therapies than biologicals, with a potential effect on psoriasis vulgaris (e.g., corticosteroids, vitamin D analogues, retinoids, immunosuppressants) within the 4 week period prior to randomisation
- Subjects using one of the following topical drugs for the treatment of psoriasis within four (4) weeks prior to study drug administration: Potent or very potent (WHO group III IV) corticosteroids PUVA or Grenz ray therapy
- Subjects using one of the following topical drugs for the treatment of psoriasis within two (2) weeks prior to study drug administration: WHO group I II corticosteroids Topical retinoids Vitamin D analogues Topical immunomodulators (e.g. macrolides) Anthracen derivatives Tar Salicylic acid UVB therapy
- 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

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: all patients apply all products	Drug: Daivobet® ointment • Once daily application 6 days a week for 3 weeks Drug: Betnovat® ointment • Once daily application 6 days a week for 3 weeks Drug: Diprosalic ointment • Once daily application 6 days a week for 3 weeks Drug: Dermovat ointment • Once daily application 6 days a week for 3 weeks Drug: Elocon ointment • Once daily application 6 days a week for 3 weeks Drug: Daivobet® ointment vehicle • Once daily application 6 days a week for 3 weeks

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame

The Absolute Change in Total Clinical Score (TCS) at End of Treatment Compared to Baseline for Daivobet® Ointment	The Total Clinical Score is the sum of three psoriasis scores (redness, thickness, and scaliness) and will range from 0 (best) to 9 (worst)	Baseline and 3 weeks
The Absolute Change in Total Clinical Score (TCS) at End of Treatment Compared to Baseline for Betnovat® Ointment	The Total Clinical Score is the sum of three psoriasis scores (redness, thickness, and scaliness) and will range from 0 (best) to 9 (worst)	Baseline and 3 weeks
The Absolute Change in Total Clinical Score (TCS) at End of Treatment Compared to Baseline for Elocon Ointment	The Total Clinical Score is the sum of three psoriasis scores (redness, thickness, and scaliness) and will range from 0 (best) to 9 (worst)	Baseline and 3 weeks
The Absolute Change in Total Clinical Score (TCS) at End of Treatment Compared to Baseline for Daivobet	The Total Clinical Score is the sum of three psoriasis scores (redness, thickness, and scaliness) and will range from 0 (best) to 9 (worst)	Baseline and 3 weeks

Ointment Vehicle		
The Absolute Change in Total Clinical Score (TCS) at End of Treatment Compared to Baseline for Dermovat Ointment	The Total Clinical Score is the sum of three psoriasis scores (redness, thickness, and scaliness) and will range from 0 (best) to 9 (worst)	Baseline and 3 weeks
The Absolute Change in Total Clinical Score (TCS) at End of Treatment Compared to Baseline for Diprosalic Ointment	The Total Clinical Score is the sum of three psoriasis scores (redness, thickness, and scaliness) and will range from 0 (best) to 9 (worst)	Baseline and 3 weeks

Collaborators and Investigators

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

Sponsor

LEO Pharma

Collaborators

No information provided

Investigators

- Study Director: Director, International Clinical Development, MD, LEO Pharma

Publications

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

General Publications

No publications available

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

Study Record Dates

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

Study Registration Dates

First Submitted
2009-02-16

First Submitted that Met QC Criteria
2009-02-16

First Posted (Estimated)
2009-02-18

Results Reporting Dates

Results First Submitted
2011-01-13

Results First Submitted that Met QC Criteria
2011-02-14

Results First Posted (Estimated)
2011-03-08

Study Record Updates

Last Update Submitted that met QC Criteria
2015-03-25

Last Update Posted (Estimated)
2015-04-14

Last Verified
2015-03

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Anti Inflammatory Agents
Glucocorticoids
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Physiological Effects of Drugs
Anti Asthmatic Agents
Respiratory System Agents
Calcium Regulating Hormones and Agents
Calcium Channel Agonists
Membrane Transport Modulators
Molecular Mechanisms of Pharmacological Action
Vasoconstrictor Agents
Vitamins
Micronutrients
Bone Density Conservation Agents
Calcitriol
Betamethasone

Study Documents

No study documents available

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

Dose Ranging Study of the Safety and Efficacy of R115966 in Plaque Psoriasis

ClinicalTrials.gov ID NCT00716144

Sponsor Stiefel, a GSK Company

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

Last Update Posted 2018 01 29

Study Details Tab

Study Overview

Brief Summary

Feedback

Eligible subjects will be randomly assigned to one of three dose regimens of oral R115866 or placebo for the treatment of severe plaque psoriasis for 12 twelve weeks. The safety and efficacy of R115866 will be evaluated during the treatment period and the 8 week post treatment follow up period.

Official Title

A Randomized, Evaluator Blind, Placebo Controlled, Parallel Group Dose Ranging Study of the Safety and Efficacy of Oral R115866 and R115866 Placebo in the Treatment of Plaque Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: Talarozole

Other Study ID Numbers

- BT0720 201 INT

Study Start

2006 06 01

Primary Completion (Actual)

2007 05 01

Study Completion (Actual)

2007 05 01

Enrollment (Actual)

176

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.

Maastricht, Netherlands
GSK Investigational Site

Nijmegen, Netherlands
GSK Investigational Site

Russian Federation

Korolev, Russian Federation
GSK Investigational Site

Lipetsk, Russian Federation
GSK Investigational Site

Moscow, Russian Federation
GSK Investigational Site

Novgorod, Russian Federation

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:

- Plaque Psoriasis with PASI greater than or equal to 10
- Male or a female who was NOT of childbearing potential (i.e., post menopausal for greater than 12 months or had a complete hysterectomy);

Exclusion Criteria:

- Spontaneously improving or rapidly deteriorating plaque psoriasis
- Guttate, pustular, erythrodermic, or other non plaque form of psoriasis
- Subject was under treatment for a heart disorder or had a history of cardiovascular disease (excluding effectively controlled hypertension)
- Any acute psychiatric condition, including an increased risk for suicide attempt, based on medical and psychiatric history
- Previous use of a psoriasis vaccine or had participated in an investigational study of a psoriasis vaccine
- Previous use of systemic immunomodulatory therapy known to affect psoriasis and to typically decrease immune cell populations
- Previous use of any systemic immunomodulatory therapy known to affect psoriasis and NOT typically to decrease immune cell populations
- Previous use of any photo therapy (including laser), photo chemotherapy, or systemic psoriasis therapy (such as systemic corticosteroids, methotrexate, retinoids, or cyclosporine) within the previous four weeks
- Pregnant or a nursing mother
- Significant coexisting hepatic, renal, or bone marrow disease, hyperlipidemia, chronic pancreatitis, osteoporosis, cancer (except non melanoma skin cancer), a positive test for human immunodeficiency virus (HIV), a history indicating adrenal cortex dysfunction

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 (Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Active Comparator: A Talarozole 0.5 mg	Drug: Talarozole • Oral Capsule Once Daily • Other Names: ◦ Rambazole ◦ R115866
Active Comparator: B Talarozole 1.0 mg	Drug: Talarozole • Oral Capsule Once Daily • Other Names: ◦ Rambazole ◦ R115866
Active Comparator: C Talarozole 2.0 mg	Drug: Talarozole • Oral Capsule Once Daily • Other Names: ◦ Rambazole ◦ R115866
Placebo Comparator: D Talarozole matching Placebo	Drug: Talarozole • Oral Capsule Once Daily • Other Names: ◦ Rambazole ◦ R115866

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Psoriasis Area Severity Index (PASI)75 Success at Visit 6	PASI75 success at Visit 6 was defined as number of participants who achieved at least 75% reduction in PASI scores at Visit 6 compared to Visit 2 (Baseline). The PASI score was determined through evaluation of body surface area (BSA) covered by plaque psoriasis in four regions (head/neck, upper extremities, trunk and lower extremities). This assessment included a combination of both degree of involvement (assessed as per the % of affected body area using a 7-point scale that ranged as 0 (0% involvement), 1 = 1-9%, 2 = 10-29%, 3 = 30-49%, 4 = 50-69%, 5 = 70-89% and 6 = 90-100%) and severity (evaluated individually using a 5-point scale that ranged as 0 = No evidence of sign, 1 = slight evidence of sign, 2 = moderate evidence of sign, 3 = marked evidence of sign and 4 = very marked, most severe evidence of sign) of erythema, induration and desquamation in each of the same four regions. PASI score ranged from 0 to 72 in 0.1-unit intervals; higher scores indicating worse psoriasis.	Week 12 (Visit 6)

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
PASI50 Success (the Reduction in PASI Score at Each Visit of at Least 50 Percent Relative to Visit 2) at	PASI50 success was defined as number of participants who achieved at least 50% reduction in PASI scores at each post baseline visit (Visit 3 to 8) compared to Visit 2 (Baseline). The PASI score was determined through evaluation of BSA covered by plaque psoriasis in four regions (head/neck, upper extremities, trunk and lower extremities). This assessment included a	Week 1 to Week 20 (Visit 3 to Visit 8)

Each Post Baseline Visit	combination of both degree of involvement (assessed as per the % of affected body area using a 7-point scale that ranged as 0 (0% involvement), 1 = 1-9%, 2 = 10-29%, 3 = 30-49%, 4 = 50-69%, 5 = 70-89% and 6 = 90-100%) and severity (evaluated individually using a 5-point scale that ranged as 0 = No evidence of sign, 1 = slight evidence of sign, 2 = moderate evidence of sign, 3 = marked evidence of sign and 4 = very marked, most severe evidence of sign) of erythema, induration and desquamation in each of the same four regions. PASI score ranged from 0 to 72 in 0.1-unit intervals; higher scores indicating worse psoriasis.	
Investigator s Global Assessment (IGA) at Each Post Baseline Visit	The IGA was used to assess the overall severity of a participant s plaque psoriasis at a particular time point and the evaluation took into consideration the three individual characteristics of plaque psoriasis (scaling, plaque elevation, and erythema). The IGA was recorded using a scale that ranged from 0 (clear), 1 = almost clear, 2 = mild, 3 = moderate to 4 (severe) in whole-unit increments; higher scores indicating worse psoriasis. Investigators did not refer to previous evaluations when conducting the IGA assessment. At every study visit, the investigator evaluated each participant s plaque psoriasis and recorded the one integer grade that best described the average, overall severity of the condition. Investigators were trained not to refer to previous assessments of the IGA, and not to base the IGA scores on any component of the PASI. Individual body regions were not assessed (as in the PASI), but rather a global evaluation for each participant at each visit was determined.	Week 1 to Week 20 (Visit 3 to Visit 8)
PASI75 at Each Post Baseline	PASI75 success was defined as number of participants who achieved at least 75% reduction in PASI scores at each post baseline visit (Visit 3	Week 1 to Week 20 (Visit

Visit Except Visit 6	to Visit 8) except Visit 6. The PASI score was determined through evaluation of BSA covered by plaque psoriasis in four regions (head/neck, upper extremities, trunk and lower extremities). This assessment included a combination of both degree of involvement (assessed as per the % of affected body area using a 7-point scale that ranged as 0 (0% involvement), 1 = 1-9%, 2 = 10-29%, 3 = 30-49%, 4 = 50-69%, 5 = 70-89% and 6 = 90-100%) and severity (evaluated individually using a 5-point scale that ranged as 0 = No evidence of sign, 1 = slight evidence of sign, 2 = moderate evidence of sign, 3 = marked evidence of sign and 4 = very marked, most severe evidence of sign) of erythema, induration and desquamation in each of the same four regions. PASI score ranged from 0 to 72 in 0.1-unit intervals; higher scores indicating worse psoriasis.	3 to Visit 8) except Week 12 (Visit 6)

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
2008-07-15

First Submitted that Met QC Criteria
2008-07-15

First Posted (Estimated)
2008-07-16

Results Reporting Dates

Results First Submitted
2017-03-10

Results First Submitted that Met QC Criteria
2017-06-28

Results First Posted
2018-01-29

Study Record Updates

Last Update Submitted that met QC Criteria
2017-06-28

Last Update Posted
2018-01-29

Last Verified

2017-05

More Information

Terms related to this study

Keywords Provided by GlaxoSmithKline (Stiefel, a GSK Company)

Psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Cytochrome P 450 Enzyme Inhibitors
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action
R 115866

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

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

ClinicalTrials.gov ID **NCT00689481**

Sponsor Stiefel, a GSK Company

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

Last Update Posted 2016 10 07

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 Foam in Subjects With Plaque type Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: U0267 Foam
- Drug: Vehicle foam

Other Study ID Numbers

- 114742
- U0267 302 (Other Identifier) (OTHER: Stiefel)

Study Start

2008 03

Primary Completion (Actual)

2008 10

Study Completion (Actual)

2008 10

Enrollment (Actual)

323

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

Mobile, Alabama, United States, 36608
Coastal Clinical Research, Inc.

California Locations

Fremont, California, United States, 94538
Center for Dermatology Cosmetic and Laser Surgery

Florida 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 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 Foam • 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 foam • 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	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
2016-08-25

Last Update Posted (Estimated)
2016-10-07

Last Verified
2016-08

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

Study Data/Documents

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

   Information Identifier

   114742

   Information Comments

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

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

   Information Identifier

   114742

   Information Comments

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

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

   Information Identifier

   114742

   Information Comments

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

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

   Information Identifier

   114742

   Information Comments

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

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

   Information Identifier

   114742

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

114742

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)

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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

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

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

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

TERMINATED

Infusion reactions during re-induction cycles after a period of no treatment. Please see "Purpose" section.

Long-Term Effects of Infliximab in the Treatment of Moderate to Severe Psoriasis [Extension of Study P04271, NCT00251641] (P04563)

ClinicalTrials.gov ID **NCT00358670**

Sponsor Merck Sharp & Dohme LLC

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

Last Update Posted 2017 04 11

Study Details Tab

Study Overview

Brief Summary

This is a long term, randomized, multi center, open label study of infliximab treatment in adults with moderate to severe plaque type psoriasis. This study is the long term extension of Study P04271

Feedback

(NCT00251641); Study P04271 is a Phase 3b, randomized, parallel group, multicenter, open label, 26 week study comparing the efficacy and safety of infliximab versus methotrexate in the treatment of adult subjects with moderate to severe plaque type psoriasis. The objectives of this study are to assess the efficacy and safety of long term maintenance therapy versus intermittent therapy with 5 mg/kg infliximab in a moderate to severe plaque type psoriasis population.

During an interim safety evaluation of the trial, a higher incidence of serious and severe infusion reactions was observed in the intermittent treatment arm, consisting of a re induction cycle (maximum of 4 infusions at 0, 2, 6 and 14 weeks) after a period of no treatment compared with the maintenance arm (infusions every 8 weeks without an interruption of treatment). Consequently, the sponsor has terminated the trial. The label will be updated to reflect this new information relating to the use of a re induction regimen with infliximab.

Official Title

A Long Term Efficacy and Safety Study of Infliximab in the Treatment of Moderate to Severe Plaque Type Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Biological: infliximab
- Biological: infliximab

Other Study ID Numbers

- P04563
- EUDRACT NUMBER:2005 005367 28

Study Start

2006 05

Primary Completion (Actual)

2009 01

Study Completion (Actual)

2009 01

Enrollment (Actual)

441

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

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

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

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

Contacts and Locations

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

No location data

Participation Criteria

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

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

Eligibility Criteria

Description

Inclusion Criteria:

- Subjects must have met all inclusion/exclusion criteria in Study P04271 (NCT00251641).
- Subjects must have been originally randomized to infliximab in Study P04271.
- Subjects must have completed the full 26 weeks of Study P04271.
- Subjects must have remained on infliximab for the full 22 weeks of treatment in Study P04271.
- Subjects must have achieved an improvement in Psoriasis Area and Severity Index (PASI) score >=75% from Baseline of Study P04271 to Week 26 of Study P04271.
- Subjects must agree to avoid prolonged sun exposure and avoid use of tanning booths or other ultraviolet light sources during the study.
- Subjects are considered eligible according to the following tuberculosis (TB) criteria:
    - Have no signs or symptoms suggestive of active TB upon medical history and/or physical examination;
    - Have had no recent close contact with a person with active TB or, if there has been such contact, will be referred to a physician specializing in TB to undergo additional evaluation and, if warranted, receive appropriate treatment for latent TB prior to or simultaneously with the first administration of study medication.
- Subjects Baseline (Visit 1) clinical laboratory tests (complete blood count, blood chemistry, and urinalysis) must be within the following parameters:
    - Hemoglobin >=10 g/dL
    - White blood cells >=3.5 x 10^9/L
    - Neutrophils >=1.5 x 10^9/L
    - Platelets >=100 x 10^9/L
    - Serum creatinine <1.5 mg/dL (or <133 umol/L)
    - Aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, and gamma glutamyltransferase levels as outlined in Protocol P04563.
    - Total bilirubin <2 x upper limit of normal [Note: If Baseline laboratory tests are not yet available, then the previous laboratory tests from Week 22 of the parent study (Study P04271) should be used for enrollment. When the Baseline laboratory tests become available, the investigator must apply the above parameters to determine a subject s eligibility.]
- Subjects must be free of any clinically significant disease (other than plaque type psoriasis or psoriatic arthritis) that would interfere with the study evaluations.
- Subjects must be willing to give written informed consent and be able to adhere to dose and visit schedules.
- Women of childbearing potential and all men must be using adequate birth control measures (eg, abstinence, oral contraceptives, intrauterine device, barrier method with spermicide, or surgical sterilization) and must continue using such measures until 6 months after receiving the last infusion of study medication.

- Female subjects of childbearing potential must have a negative urine pregnancy test at Baseline.

Exclusion Criteria:

- Subjects who have any significant ongoing adverse events (AEs) or AEs from Study P04271 (NCT00251641) that would prohibit further treatment with infliximab at the time of entry.
- Subjects originally randomized to methotrexate or subjects who received methotrexate at any time during their participation in Study P04271.
- Subjects who have non plaque forms of psoriasis (eg, erythrodermic, guttate, or pustular).
- Subjects who have current drug induced psoriasis (eg, a new onset of psoriasis or an exacerbation of psoriasis from beta blockers, calcium channel blockers, or lithium).
- Female subjects who are pregnant, nursing, and both men and women who are planning pregnancy during the study period or during the 6 months after receiving of the last infusion of study medication.
- Subjects who are in a situation or have any condition that, in the opinion of the investigator, may interfere with optimal participation in the study.
- Subjects who are staff personnel directly involved with this study.
- Subjects who are family members of the investigational study staff.

Ages Eligible for Study

18 Years to 75 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

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

How is the study designed?

Design Details

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

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Active Comparator: Maintenance Infliximab Infliximab 5 mg/kg by body weight every 8 weeks	Biological: infliximab • Infliximab maintenance therapy intravenous (IV) infusion every 8 weeks, 5 mg/kg body weight (first infusion at Week 4/Visit 2). • Other Names: ◦ SCH 215596 ◦ Remicade
Experimental: Intermittent Infliximab Infliximab 5 mg/kg by body weight at Weeks 0, 2, 6 and 14 following a 50% reduction in Psoriasis Area and Severity Index (PASI) from the Study P04271 Baseline	Biological: infliximab • Infliximab intermittent therapy: Paricipants will receive no infliximab treatment until the Week 26 improvement in PASI from Baseline (original Study P04271 [NCT00251641] Baseline) is reduced by more than 50%. At that time, participants will receive an infliximab infusion, 5 mg/kg body weight. Participants may receive additional infusions at 0, 2, 6, and 14 weeks after the first infusion of the cycle (ie, a maximum of 4 infusions in each infusion cycle) as needed until they respond, defined as a >=75% improvement in PASI from the original Baseline in Study P04271. Subjects will receive no further treatment until they relapse again (ie, improvement in PASI from Baseline is reduced by more than 50%), at which time participants will receive another infusion cycle of up to 4 infusions, as described above. Throughout the study,

	intermittent treatment infusion cycles will be repeated whenever participants relapse. • Other Names: ◦ SCH 215596 ◦ Remicade

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants Who Achieved Psoriasis Area and Severity Index 75 (PASI75) Response at Week 128	PASI75 defined as the number of participants who achieved a >=75% improvement in Psoriasis Area and Severity Index (PASI) from the original Baseline in Study P04271 (NCT00251641).	128 weeks

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants Who Achieved PASI75 Response at Week 52	PASI75 defined as the number of participants who achieved a >=75% improvement in PASI from the original Baseline in Study P04271 (NCT00251641)	52 weeks
Number of Participants Who Achieved PASI75	PASI75 defined as the number of participants who achieved a >=75% improvement in PASI from the original Baseline in Study P04271 (NCT00251641)	100 Weeks

Response at Week 100		
PASI 6-month Area Under the Curve (AUC); (Time Adjusted Total PASI Score Over the 6 Month Period)	The PASI 6-month AUC is a time adjusted total PASI score over the 6 month (180 days) period. The AUC is a continuous measurement (not a score on a scale); a lower value is considered better and a higher value is considered worse. The weighted average PASI score over 6 months (using all available PASI scores during a 6 month period [from Day 0 to 180 days]) is obtained by using PASI 6-month AUC /180 days.	Day 0 to 180 days
PASI 12-month AUC (Time Adjusted Total PASI Score Over the 12 Month Period)	The PASI 12-month AUC is a time adjusted total PASI score over the 12 month (360 days) period. The AUC is a continuous measurement (not a score on a scale); and a lower value is considered better. The weighted average PASI score over 12 months (using all available PASI scores during a 12 month period [from Day 0 to 360 days]) is is obtained by using PASI 12-month AUC /360 days.	Day 0 to 360 days

Collaborators and Investigators

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

Sponsor

Merck Sharp & Dohme LLC

Collaborators

No information provided

Investigators

No information provided

Publications

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

General Publications

No publications available

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

Study Record Dates

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

Study Registration Dates

First Submitted
2006-07-31

First Submitted that Met QC Criteria
2006-07-31

First Posted (Estimated)
2006-08-01

Results Reporting Dates

Results First Submitted
2010-04-08

Results First Submitted that Met QC Criteria
2010-10-22

Results First Posted (Estimated)
2010-11-19

Study Record Updates

Last Update Submitted that met QC Criteria
2017-03-13

Last Update Posted
2017-04-11

Last Verified
2017-03

More Information

Terms related to this study

Additional Relevant MeSH Terms

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

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Yes

IPD Plan Description

http://www.merck.com/clinical trials/pdf/Merck%20Procedure%20on%20Clinical%20Trial%20Data%20Access%20Final_Updated%20July_9_2014.pdf

http://engagezone.msd.com/ds_documentation.php

Study Documents

No study documents available

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

Mechanism of Action Study for Psoriasis (MOA)

ClinicalTrials.gov ID NCT00932113

Sponsor Tufts Medical Center

Information provided by Tufts Medical Center (Responsible Party)

Last Update Posted 2017 08 31

Study Details Tab

Study Overview

Brief Summary

The objective of this study is to compare the mechanism of action between adalimumab and methotrexate in subjects with psoriasis.

Detailed Description

Feedback

Both methotrexate and adalimumab are FDA approved drugs for the treatment of moderate to severe psoriasis. The two treatments, methotrexate and adalimumab, both show efficacy for psoriasis, however their profiles differ. In the CHAMPION Study, more adalimumab treated, moderate to severe psoriasis patients achieved a PASI 75 after 16 weeks compared to those treated with methotrexate (80% vs. 36%). The reason for this difference is poorly understood. No direct comparative mechanism of action studies in psoriasis patients between methotrexate and adalimumab (or any tumor necrosis factor blocker) has been reported.

With etanercept, another tumor necrosis factor blocker, the in vivo mechanism has been studied with some scientific rigor. These studies demonstrate that etanercept down regulates multiple pro inflammatory pathways (as shown in Table 1 of the protocol).

To date, there are no similar studies with adalimumab or methotrexate.

In order to understand the molecular and cellular basis for the differential clinical efficacy of adalimumab and methotrexate, it is essential to compare their mechanisms of action in psoriatic plaques. Biopsies will be performed, and we will study biomarkers in this proposal with immunohistochemistry, real time polymerase chain reaction, and gene arrays.

Official Title

An Investigator Initiated, Assessor Blinded, Randomized Study Comparing the Mechanism of Action of Adalimumab to Methotrexate in Subjects With Moderate to Severe Chronic Plaque Psoriasis.

Conditions

Psoriasis

Intervention / Treatment

- Drug: Methotrexate
- Drug: Adalimumab (Humira)

Other Study ID Numbers

- MOA
- ABT 08 030 (Other Grant/Funding Number) (OTHER_GRANT: AbbVie)

Study Start

2009 06

Primary Completion (Actual)

2011 12

Study Completion (Actual)

2017 05 01

Enrollment (Actual)

33

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

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

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

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.

United States

Massachusetts Locations

Boston, Massachusetts, United States, 02111

Tufts Medical Center, Department of 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:

- Adults 18 85 years of age with moderate to severe psoriasis, in general good health as determined by the PI based upon the results of medical history, laboratory profile, and physical examination, and who are candidates for systemic or phototherapy
- Presence of a psoriatic plaque of >2cm in an area which can be biopsied repeatedly.
- Men must agree to avoid impregnating a woman while on this study.
- Women are eligible to participate in the study if they meet one of the following criteria:
    - Women who are postmenopausal (>1 year), sterile, or hysterectomized
    - Women of childbearing potential must undergo monthly pregnancy testing during the study and agree to use two of the following methods of contraception throughout and for 60 days after the last dose of study drug:
        - Oral contraceptives
        - Transdermal contraceptives
        - Injectable or implantable methods
        - Intrauterine devices
        - Barrier methods (diaphragm or condom with spermicide)
        - Abstinence and Tubal Ligation are also considered a form of Birth control

Exclusion Criteria:

- Patients <18 or >85 years old
- Absence of a psoriatic plaque >2cm in diameter
- Active guttate, erythrodermic, or pustular psoriasis at the time of the screening visit
- Evidence of skin conditions at screening (e.g. eczema) that would interfere with evaluations of the effect of study medication
- Inability to understand the consent process
- Receipt of any investigational drugs, psoralen+ultraviolet A or oral systemic treatments within 4 weeks of study drug initiation
- Biologics within 3 months of study initiation
- Topical steroids, topical vitamin A or D analog preparations, Ultraviolet B therapy or anthralin within 2 weeks of study drug initiation. (Exception stable regimen of class I II topical steroids on scalp, axillae, and groin)
- Methotrexate within 6 weeks of study initiation
- History of treatment with adalimumab
- History of primary non response to methotrexate, infliximab or etanercept
- History of discontinuation of methotrexate or tumor necrosis factor (TNF) blocker for a safety related reason that makes it unwise to restart either type of drug
- Any internal malignancy within 5 years (excluding fully excised cutaneous basal cell or squamous cell carcinoma)
- Pregnancy, not practicing effective birth control, or inability to practice safe sex during the length of the study
- Lactation

- Subjects who have known hypersensitivity to adalimumab or methotrexate or any of its components or who is known to have antibodies to etanercept
- History of alcohol or drug abuse one year before and during the study
- Known HIV positive status or any other immune suppressing disease
- Presence of a grade 3 or 4 infection <30 days prior to the screening visit, between the screening visit and the first day of treatment on study, or any time during the study that in the opinion of the PI would preclude participation in the study
- Any grade 3 or 4 adverse event, or laboratory toxicity, at the time of the screening visit or at any time during the study, which in the opinion of the PI would, preclude participation in the study
    - Serum creatinine >3.0 mg/dL (265 micromoles/L)
    - Serum potassium <3.5 mmol/L or > 5.5 mmol/L
    - Serum alanine aminotransferase or aspartate aminotransferase >3 times the upper limit of normal for the lab
    - Platelet count <100,000/mm3
    - White blood cell count <3,000/mm3
    - Hgb, Hct, or red blood cell outside 30% of the upper or lower limits of normal for the Lab
- Receipt of live vaccines 1 month prior to or while on study
- History of tuberculosis, and/or a positive PPD skin test/chest x ray at screening without appropriate treatment treatment of latent tuberculosis (for those with positive PPD tests) must be initiated prior to therapy with adalimumab or methotrexate
- Chronic hepatitis B or C infection, history of multiple sclerosis, transverse myelitis, optic neuritis or epilepsy

Ages Eligible for Study

18 Years to 85 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

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

How is the study designed?

Design Details

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

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Active Comparator: Adalimumab Dosing will be on day 1 and then weekly. For the injections, dosing will occur according to product recommendations. Patients will receive 80mg adalimumab (2 pre-filled syringes, each with 40mg) on day 1, and then 40mg on week 1 and then every 2 weeks (from week 1 through week 15).	Drug: Adalimumab (Humira) • 2 cohorts (Randomized 1:1 adalimumab:methotrexate). Subjects will receive treatment on Day 1 (baseline visit) and then weekly or every 2 weeks for 16 weeks. • Other Names: ◦ Humira
Active Comparator: Methotrexate (MTX) Patients will be dosed according to the CHAMPION study in single weekly doses of methotrexate: 7.5mg at week 0, 10mg at week two, and 15mg at week 4 for all patients. For each subject if the PASI did not decrease by at least 50% from baseline (PASI-50) at week 8, dosing will be increased to 20mg per	Drug: Methotrexate • 2 cohorts (Randomized 1:1 adalimumab:methotrexate). Subjects will receive treatment on Day 1 (baseline visit) and then weekly or every 2 weeks for 16 weeks. Methotrexate-treated patients will then receive 16 weeks of adalimumab at the end of study. • Other Names: ◦ Methotrexate (MTX) ◦ Folic Acid Drug: Adalimumab (Humira)

week; the dose will be maintained at 15mg per week if PASI-50 was achieved at week 8. If PASI-50 was not achieved at week 12, dosing will be increased to 25mg per week; the dose will be maintained at 20mg per week if the PASI-50 was achieved at week 12. All patients on methotrexate will also receive a dietary supplement of oral folate (5mg per week). Methotrexate-treated patients will then receive 16 weeks of adalimumab at the end of study.	• 2 cohorts (Randomized 1:1 adalimumab:methotrexate). Subjects will receive treatment on Day 1 (baseline visit) and then weekly or every 2 weeks for 16 weeks. • Other Names: ◦ Humira

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Biologic Activity Endpoints	Histologic and Immunohistochemistry endpoints; Relative messenger RNA gene expression (normalized to HARP); and Gene Arrays.	Weeks 0, 1, 2, 4 and 16

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Clinical Endpoints for Psoriasis: PASI 75	PASI 75 is the percent of subjects who experience an improvement in PASI (Psoriasis Area and Severity Index) score of at least 75% from their baseline PASI score.	Weeks 0 and week 16
Clinical Endpoints for Psoriasis: Physicians Global Assessment (PGA) Clear or Almost Clear (PGA 0-1)		Week 0 and Week 16
Clinical Endpoints for Psoriasis: % Body Surface Area		Week 0 and week 16
Clinical Endpoints for Psoriasis: Target Lesion Score	The lesion score of a single psoriatic plaque selected at baseline. Total range is 0 - 12 with 0 being clear and 12 representing the most severe disease. The target lesion score is composed of scale, erythema, and induration, each parameter is scored 0 (clear) through 4 (very severe). Totals are summed for target lesion score. S+E+I = TLS	Week 0 and Week 16
Clinical Endpoints for Psoriasis: Photography Completed		Week 0 and Week 16

Other Outcome Measures

Outcome Measure	Measure Description	Time Frame

Additional Gene Analysis (Ongoing)	A single, long-term follow-up visit will be done for all available subjects for additional pharmacogenetic analysis. The goal in collecting DNA from psoriasis patients is to determine if individual subjects have gene variants associated with increased incidence of psoriasis. The investigators plan on analyzing variants using single nucleotide polymorphism (SNP) analysis by high-throughput DNA sequencing. This patient genetic information may allow us to correctly interpret data collected about gene expression levels in affected or non-affected skin. Additionally genetic typing may lead to cogent personalized health care (PHC) strategies for the identification of psoriasis drug responders/non-responders, patients who achieve durable disease remission post-treatment, and/or pharmacodynamic markers, as examples.	long-term follow-up visit 4- 6 years post end of study

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, M.D., PhD., Tufts Medical Center, Department of Dermatology

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

- Malaviya R, Sun Y, Tan JK, Magliocco M, Gottlieb AB. Induction of lesional and circulating leukocyte apoptosis by infliximab in a patient with moderate to severe psoriasis. J Drugs Dermatol. 2006 Oct;5(9):890 3. (https://pubmed.ncbi.nlm.nih.gov/17039656)
- Malaviya R, Sun Y, Tan JK, Wang A, Magliocco M, Yao M, Krueger JG, Gottlieb AB. Etanercept induces apoptosis of dermal dendritic cells in psoriatic plaques of responding patients. J Am Acad Dermatol. 2006 Oct;55(4):590 7. doi: 10.1016/j.jaad.2006.05.004. Epub 2006 Jul 3. (https://pubmed.ncbi.nlm.nih.gov/17010737)
- Gottlieb AB, Chamian F, Masud S, Cardinale I, Abello MV, Lowes MA, Chen F, Magliocco M, Krueger JG. TNF inhibition rapidly down regulates multiple proinflammatory pathways in psoriasis plaques. J Immunol. 2005 Aug 15;175(4):2721 9. doi: 10.4049/jimmunol.175.4.2721. (https://pubmed.ncbi.nlm.nih.gov/16081850)
- Tan JK, Aphale A, Malaviya R, Sun Y, Gottlieb AB. Mechanisms of action of etanercept in psoriasis. J Investig Dermatol Symp Proc. 2007 May;12(1):38 45. doi: 10.1038/sj.jidsymp.5650037. (https://pubmed.ncbi.nlm.nih.gov/17502868)
- Lizzul PF, Aphale A, Malaviya R, Sun Y, Masud S, Dombrovskiy V, Gottlieb AB. Differential expression of phosphorylated NF kappaB/RelA in normal and psoriatic epidermis and downregulation of NF kappaB in response to treatment with etanercept. J Invest Dermatol. 2005 Jun;124(6):1275 83. doi: 10.1111/j.0022 202X.2005.23735.x. (https://pubmed.ncbi.nlm.nih.gov/15955104)

*** 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
2009-06-30

First Submitted that Met QC Criteria
2009-07-01

First Posted (Estimated)
2009-07-03

Results Reporting Dates

Results First Submitted
2016-09-27

Results First Submitted that Met QC Criteria
2017-06-01

Results First Posted
2017-07-02

Study Record Updates

Last Update Submitted that met QC Criteria
2017-08-01

Last Update Posted
2017-08-31

Last Verified
2017-08

More Information

Terms related to this study

Keywords Provided by Tufts Medical Center

tumor necrosis factor (TNF) inhibitor
tumor necrosis factor (TNF) blockade
Methotrexate
treatment
mechanism
psoriasis

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Abortifacient Agents, Nonsteroidal
Abortifacient Agents
Reproductive Control Agents
Physiological Effects of Drugs
Antimetabolites, Antineoplastic
Antimetabolites
Molecular Mechanisms of Pharmacological Action
Antineoplastic Agents
Dermatologic Agents
Enzyme Inhibitors
Folic Acid Antagonists
Immunosuppressive Agents
Immunologic Factors
Antirheumatic Agents
Nucleic Acid Synthesis Inhibitors
Tumor Necrosis Factor Inhibitors
Anti Inflammatory Agents
Hematinics
Vitamin B Complex
Vitamins
Micronutrients
Folic Acid
Adalimumab
Methotrexate

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

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

Safety and Efficacy of Adalimumab in Patients Who Showed an Unsatisfactory Response to Etanercept

ClinicalTrials.gov ID NCT00927069

Sponsor Innovaderm Research Inc.

Information provided by Innovaderm Research Inc. (Responsible Party)

Last Update Posted 2011 09 09

Study Details Tab

Study Overview

Brief Summary

This study will provide data on additional therapeutic benefits in administering Adalimumab in patients with plaque psoriasis that showed an unsatisfactory response after at least 3 months of treatment with etanercept.

Feedback

Detailed Description

A total of 50 patients with psoriasis vulgaris who showed an unsatisfactory response to etanercept 50 mg twice a week followed by 50 mg once a week and a total of 50 patients who showed an unsatisfactory response to etanercept 50 mg twice a week without dose reduction will be recruited. All patients will receive adalimumab 40 mg every other week (EOW) for 12 weeks. Patients who fail to reach a physicians global assessment (PGA) of clear or almost clear at week 12 will have an increase in adalimumab to 40 mg every week (EW) for an additional 12 weeks. Patients who reach a PGA of clear or almost clear at week 12 will continue to receive adalimumab at 40 mg EOW for an additional 12 weeks. Patients will be evaluated for safety and efficacy every 4 weeks for a total of 24 weeks. PASI, BSA and PGA will be performed at each visit. Routine chemistry, hematology and urinalysis will be performed every 4 weeks.

The percentage of patients achieving a physicians global assessment (PGA) of clear or almost clear after at least 12 weeks of adalimumab will be calculated for patients who had shown an unsatisfactory response to 3 months of etanercept at 50 mg twice a week without dose reduction as well as for patients who had shown an unsatisfactory response to 3 months of etanercept at 50 mg twice a week followed by 50 mg once a week.

A physicians global assessment (PGA) of clear is defined by no plaque elevation over normal skin. There is no scale. Erythema is perceptible as hyperpigmentation, pigmented macules, diffuse faint pink or red coloration.

A physicians global assessment (PGA) of almost clear is defined as follows: It is possible but difficilt to ascertain whether there is a slight elevation above normal skin. There is scaling in the form of surface dryness with some white coloration. Erythema is up to a definite red coloration.

Official Title

Open Label Study to Evaluate the Efficacy and Safety of Adalimumab in Patients With Plaque Psoriasis Who Showed an Unsatisfactory Response to Etanercept

Conditions

Plaque Psoriasis

Intervention / Treatment

- Drug: Adalimumab every other week
- Drug: Adalimumab Every Week

Other Study ID Numbers

- Inno 6002

Study Start

2007 03

Primary Completion (Actual)

2008 09

Study Completion (Actual)

2008 12

Enrollment (Actual)

85

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) 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.

Canada

Quebec, Canada, G1J 1X7
Centre de Recherche Clinique Martin

Gilbert inc et Centre Dermatologie
Maizerets

Click to view interactive map

Manitoba Locations

Winnipeg, Manitoba, Canada, R3C 0N2
Winnipeg Clinic

Newfoundland and Labrador

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 with plaque psoriasis with documentation of an unsatisfactory response to etanercept as defined by either:
    1. Failure to present a PGA of clear or almost clear after at least 3 months of etanercept at 50 mg twice a week OR;
    2. Failure to present a PGA of clear or almost clear after at least 3 months of etanercept at 50 mg twice a week followed by a dose reduction to 50 mg once a week. To be eligible these patients must have reached a PGA of clear or almost clear after at least 3 months of etanercept at 50 mg twice a week followed by a loss of PGA of clear or almost clear at anytime after a dose reduction to 50 mg of etanercept once a week.
- Subject presents a PGA of 3 or more at baseline visit.
- Subject with plaque psoriasis at screening that is severe enough to be candidate for systemic therapy.
- Subject is 18 to 80 years of age .
- Female subject is either not of childbearing potential, defined as postmenopausal for at least 1 year or surgically sterile (bilateral tubal ligation, bilateral oophorectomy or hysterectomy), or is of childbearing potential and practicing one of the following methods of birth control throughout the study and for 150 days after study completion:
    1. condoms, sponge, foams, jellies, diaphragm or IUD;
    2. contraceptives (oral or parenteral) for three months prior to study drug administration;
    3. a vasectomized partner;
- Female subjects of childbearing potential must have a negative serum pregnancy test at the Screening visit.
- Subject is judged to be in good general health as determined by the principal investigator based upon the results of medical history, laboratory profile, physical examination, and CXR performed at Screening.
- Subjects will be evaluated for latent TB infection with a PPD test and CHX. Subjects who demonstrate evidence of latent TB infection (either PPD more than or equal to 5 mm of induration, irrespective of BCG vaccination status and negative CXR findings for active TB, and/or suspicious CXR findings will not be allowed to participate in the study.
- Subjects must be able and willing to provide written informed consent and comply with the requirements of this study protocol.
- Subjects must be able and willing to self administer SC injections or have a qualified person available to administer SC injections.

Exclusion Criteria:

- Subject has other active skin diseases or skin infections (bacterial, fungal, or viral) that may interfere with evaluation of psoriasis or with subject s safety.

- Subject has a history of an allergic reaction or significant sensitivity to constituents of study drug, including latex (a component of the pre filled syringe).
- Subject who has used topical treatments in the last 4 weeks of the etanercept treatment period when the response to etanercept was evaluated as unsatisfactory must use the same topical therapy with the same agents applied in the same manner and with the same application frequency for two weeks prior to the baseline visit as well as during the entire trial. The use of any other topical treatment for psoriasis is prohibited except for allowed treatments.
- Subject who has used UVB phototherapy, excessive sun exposure, phototherapy or any non biological systemic therapy for the treatment of psoriasis less than 30 days before day 0. Investigational chemical agents must be discontinued at least 30 days or 5 half lives prior to the Baseline visit (whichever is longer).
- Subject who has used any biological therapy (apart from etanercept) for the treatment of psoriasis less than 3 months (90 days) before day 0. Etanercept must be discontinued before baseline but a washout period is not required.
- Subject is taking or requires oral or injectable corticosteroids during the study. Inhaled corticosteroids for stable medical conditions are allowed.
- Subjects for whom documentation of unsatisfactory response to etanercept was obtained while the subject was under combination treatment with any of the following: UVB phototherapy, PUVA therapy, prednisone, methotrexate, acitretin, cyclosporine or any other systemic or biologic drug (apart from etanercept).
- Subject has a poorly controlled medical condition, such as uncontrolled diabetes with documented history of recurrent infections, unstable ischemic heart disease, congestive heart failure, recent stroke and any other condition which, in the opinion of the investigator, would put the subject at risk if participating in the study.
- Subject has history of neurologic symptoms suggestive of central nervous system (CNS) demyelinating disease.
- Subject has history of cancer or lymphoproliferative disease other than a successfully treated non metastatic cutaneous squamous cell or basal cell carcinoma and/or localized carcinoma in situ of the cervix.
- Subject has a history of listeriosis, treated or untreated TB, persistent chronic infections, or recent active infections requiring hospitalization or treatment with intravenous anti infectives within 30 days or oral anti infectives within 14 days prior to the Baseline visit.
- Subject who has received any live attenuated vaccine 28 days or less before baseline.
- Subject with hepatitis B or hepatitis C viral infection.
- Subject with any of the following: hemoglobin ≤ 10 g/L, white blood cells ≤ 3.0 X 109/L, platelet counts ≤130 X 109/L, ALT ≥ 2 times the upper limit of normal, AST ≥ 2 times the upper normal limit, total bilirubin ≥ 2 times the upper normal limit or creatinine ≥ 150 mmol/L.
- Subject currently uses or plans to use anti retroviral therapy at any time during the study.
- Subject is known to have immune deficiency or is immunocompromised.
- Female subject who is pregnant or breast feeding or considering becoming pregnant during the study or for 150 days after the last dose of study medication.
- Subject has a history of clinically significant drug or alcohol abuse in the last year.
- Subject is considered by the investigator, for any reason, to be an unsuitable candidate for the study.

- Subject has erythrodermic psoriasis, generalized or localized pustular psoriasis, medication induced or medication exacerbated psoriasis, or new onset guttate psoriasis.

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

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

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Group A Patients who have shown an unsatisfactory response to 3 months of etanercept 50 mg twice a week without dose reduction prior to screening.	Drug: Adalimumab every other week • Adalimumab 40mg injection every other week for 24 weeks • Other Names: ◦ HUMIRA
Experimental: Group B Patients who showed a satisfactory response to 3 months or more of etanercept 50 mg twice a week followed by a loss of response after dose reduction to 50 mg etanercept once a week prior to screening.	Drug: Adalimumab every other week • Adalimumab 40mg injection every other week for 24 weeks • Other Names: ◦ HUMIRA
Experimental: Group A dose increase at Week 12 Patients in group A who - after 12 weeks of adalimimab 40 mg every other week in this study - failed to reach a physician s global assessment (PGA) of clear or	Drug: Adalimumab Every Week • Adalimumab 40mg injection every week for the last 12 weeks of study. • Other Names: ◦ HUMIRA

almost clear and had a dose increase to 40 mg adalimimab every week for another 12 weeks.	
Experimental: Group B dose increase at Week 12 Patients in group B who - after 12 weeks of adalimimab 40 mg every other week in this study - failed to reach a physicians global assessment (PGA) of clear or almost clear and had a dose increase to 40 mg adalimimab every week for another 12 weeks.	Drug: Adalimumab Every Week • Adalimumab 40mg injection every week for the last 12 weeks of study. • Other Names: ◦ HUMIRA

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Patients From Group B Who Achieve a Physicians Global Assessment (PGA) of Clear	Efficacy of adalimumab 40 mg every other week in patients in Group B by calculating the number of patients who achieve a PGA of clear or almost clear at Week 12. Clear is defined by no plaque elevation above normal skin. There is no scale. Erythema is perceptible as hyperpigmentation, pigmented macules, diffuse faint pink or red coloration.	12 weeks

or Almost Clear at Week 12.	Almost Clear is defined as follows: It is possible but difficult to ascertain whether there is a slight elevation above normal skin. There is scaling in the form of surface dryness with some white coloration. Erythema is up to a difinite red coloration.	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Patients From Group A Who Achieve a Physicians Global Assessment (PGA) of Clear or Almost Clear at Week 12.	Efficacy of adalimumab in patients from Group A who achieve a Physicians Global Assessment (PGA) of clear or almost clear at week 12. Clear is defined by no plaque elevation above normal skin. There is no scale. Erythema is perceptible as hyperpigmentation, pigmented macules, diffuse faint pink or red coloration. Almost Clear is defined as follows: It is possible but difficult to ascertain whether there is a slight elevation above normal skin. There is scaling in the form of surface dryness with some white coloration. Erythema is up to a difinite red coloration.	12 weeks
Number of Patients From Group B Who Achieve a Physicians Global Assessment (PGA) of Clear or Almost Clear at Week 24 After a Dose	Efficacy of adalimumab in patients from Group B who achieve a Physicians global assessment (PGA) of clear or almost clear at Week 24. Clear is defined by no plaque elevation above normal skin. There is no scale. Erythema is perceptible as hyperpigmentation, pigmented macules, diffuse faint pink or red coloration. Almost Clear is defined as follows: It is possible but difficult to ascertain whether there is a slight	24 weeks

Increase to 40mg Adalimumab Every Week.	elevation above normal skin. There is scaling in the form of surface dryness with some white coloration. Erythema is up to a difinite red coloration.	
Number of Patients From Group A Who Achieve a Physicians Global Assessment (PGA) of Clear or Almost Clear at Week 24 After a Dose Increase to 40mg Adalimumab Every Week.	Efficacy of adalimumab in patients from Group A who achieve a Physicians Global Assessment (PGA) of clear or almost clear at Week 24. Clear is defined by no plaque elevation above normal skin. There is no scale. Erythema is perceptible as hyperpigmentation, pigmented macules, diffuse faint pink or red coloration. Almost Clear is defined as follows: It is possible but difficult to ascertain whether there is a slight elevation above normal skin. There is scaling in the form of surface dryness with some white coloration. Erythema is up to a difinite red coloration.	24 weeks
Total Number of Adverse Events for All Patients in the Study.	Safety of adalimumab in patients with plaque psoriasis that showed an unsatisfactory response after at least 3 months of therapy with etanercept	24 weeks

Collaborators and Investigators

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

Sponsor

Innovaderm Research Inc.

Collaborators

- Abbott

Investigators

- Principal Investigator: Robert Bissonnette, MD, Innovaderm Research 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
2009-06-22

First Submitted that Met QC Criteria
2009-06-23

First Posted (Estimated)
2009-06-24

Results Reporting Dates

Results First Submitted
2010-01-18

Results First Submitted that Met QC Criteria
2010-07-30

Results First Posted (Estimated)
2010-08-24

Study Record Updates

Last Update Submitted that met QC Criteria
2011-09-01

Last Update Posted (Estimated)
2011-09-09

Last Verified
2011-09

More Information

Terms related to this study

Keywords Provided by Innovaderm Research Inc.

Adalimumab

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

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

Safety and Efficacy Study of A Novel Ointment to Treat Plaque Type Psoriasis

ClinicalTrials.gov ID **NCT00755196**

Sponsor Pfizer

Information provided by Pfizer (Responsible Party)

Last Update Posted 2017 03 06

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to evaluate the safety and efficacy of AN2728 Ointment, 5%, compared to Ointment Vehicle, applied twice daily for 12 weeks, in the treatment of plaque type psoriasis

Feedback

Detailed Description

This is a single center, randomized, double blind, vehicle controlled, bilateral design. Patients will apply both test articles, AN2728 Ointment, 5%, and Ointment 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, 5%, Versus Ointment Vehicle in the Treatment of Patients With Plaque Type Psoriasis

Conditions

Psoriasis

Intervention / Treatment

- Drug: AN2728
- Drug: Ointment vehicle

Other Study ID Numbers

- AN2728 PSR 202
- C3291015 (Other Identifier) (OTHER: Pfizer)

Study Start

2008 09

Primary Completion (Actual)

2008 12

Study Completion (Actual)

2008 12

Enrollment (Actual)

30

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

Distrito Federal Locations

Mexico City, Distrito Federal, Mexico, 06700
IMIC

Click to view interactive map

Participation Criteria

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

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

Eligibility Criteria

Description

Inclusion Criteria:

1. Male or female >18 years of age at time of enrollment
2. The clinical diagnosis of stable plaque psoriasis
3. Two target plaques of similar severity
    - ≥ 5 cm2 but ≤ 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 distinct plaques located on the trunk. Plaques located on the trunk must be separated by at least 10 cm and will be designated by the Investigator as either left/right or front/back or upper/lower
    - 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 individual plaques
4. Normal or not clinically significant screening laboratory results
5. Willing and able to apply study drug as directed, comply with study instructions and commit to all follow up visits
6. Ability to understand, agree to and sign the study Informed Consent Form (ICF) prior to initiation of any protocol related procedures

Exclusion Criteria:

1. Any dermatological conditions that could interfere with clinical evaluations or any disease state or physical condition which might expose the patient to an unacceptable risk by study participation
2. Any underlying disease(s) or other dermatological conditions that require the use of exclusionary topical or systemic therapy (see below).
3. Known sensitivity to any of the components of the study medication
4. Spontaneously improving or rapidly deteriorating psoriatic plaques or pustular/exfoliative, guttate, erythrodermic or other non plaque form of psoriasis
5. Concomitant use of topical or systemic therapies that might alter the course of psoriasis
6. Females of child bearing potential. Females must be post menopausal or surgically sterile (oophorectomy).
7. Washout periods of:
    - Topical drugs that might alter the course of psoriasis: 2 weeks
    - Oral retinoids: 8 weeks
    - Non retinoid systemic drugs that might alter the course of psoriasis: 4 weeks
    - PUVA: 4 weeks
    - UVB therapy: 4 weeks
    - Use of emollients/moisturizers on area(s) to be treated: 2 days to baseline visit
8. AIDS or AIDS related illness
9. Concurrent participation in another drug research study or within 30 days of enrollment
10. Use of lithium or hydroxychloroquine containing products (i.e. Plaquenil)

11. Use of a beta blocking medication (i.e. propranolol) if the dose has not been stabilized for at least 3 months

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: 1 AN2728 Ointment, 5%	Drug: AN2728 • AN2728 Ointment, 5%, twice daily for 12 weeks • Other Names: ◦ AN2728 Ointment, 5%
Placebo Comparator: 2 AN2728 Ointment vehicle	Drug: Ointment vehicle • Ointment vehicle, twice daily for 12 weeks

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With Lowering of Overall Target Plaque Severity Score (OTPSS) at Day 84	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 indicated more severity of a plaque. In this outcome measure, percentage of participants with reduced OTPSS at Day 84 were reported and comparison of ointment and vehicle treated plaque was given as Ointment treated plaque versus (vs.) vehicle treated plaque and Vehicle treated plaque vs. ointment treated plaque.	Day 84

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Participants With Lowering of Overall Target Plaque Severity Score (OTPSS) At Day 7, 14, 28, 42, 56, 70, 91	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 indicated more severity of a plaque. In this outcome measure, percentage of participants with reduced OTPSS at Day 7, 14, 28, 42, 56, 70 and 91 were reported and comparison of ointment and vehicle treated plaque was given as Ointment treated plaque vs. vehicle treated plaque and Vehicle treated plaque vs. ointment treated plaque.	Day 7, 14, 28, 42, 56, 70, 91

Collaborators and Investigators

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

Sponsor

Pfizer

Collaborators

No information provided

Investigators

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

Publications

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

General Publications

No publications available

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

Study Record Dates

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

Study Registration Dates

First Submitted
2008-09-17

First Submitted that Met QC Criteria
2008-09-17

First Posted (Estimated)
2008-09-18

Results Reporting Dates

Results First Submitted
2017-01-12

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

Results First Posted
2017-03-06

Study Record Updates

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

Last Update Posted
2017-03-06

Last Verified
2017-01

More Information

Terms related to this study

Keywords Provided by Pfizer

Plaque Type Psoriasis
Topical

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

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 Comparison of 122-0551 Foam Versus Vehicle Foam in Subjects With Plaque Psoriasis

ClinicalTrials.gov ID **NCT02367911**

Sponsor Therapeutics, Inc.

Information provided by Therapeutics, Inc. (Responsible Party)

Last Update Posted 2018 11 08

Study Details Tab

Study Overview

Brief Summary

This Phase 3 study has been designed to determine and compare the efficacy and safety of 122 0551 Foam and Vehicle Foam applied twice daily for two weeks in subjects with plaque psoriasis.

Official Title

A Multicenter, Randomized, Double Blind, Parallel Group Comparison of 122 0551 Foam Versus Vehicle Foam in Subjects With Plaque Psoriasis

Conditions

Plaque Psoriasis

Intervention / Treatment

- Drug: 122 0551 Foam
- Drug: Vehicle Foam

Other Study ID Numbers

- 122 0551 305

Study Start

2015 01

Primary Completion (Actual)

2015 08

Study Completion (Actual)

2017 02

Enrollment (Actual)

144

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, 35205
Total Skin and Beauty Dermatology Center, PC

California Locations

San Diego, California, United States, 92122
UCSD 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 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 a physical condition which, in the investigator s opinion, might impair evaluation of plaque psoriasis, or which exposes the subject to an unacceptable risk by study participation.
- 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.

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 122-0551 Foam, topically applied twice daily for two weeks	Drug: 122-0551 Foam • 122-0551 Foam applied twice daily to treat psoriasis
Placebo Comparator: Vehicle Arm Vehicle Foam, topically applied twice daily for two weeks	Drug: Vehicle Foam • Vehicle Foam applied twice daily to treat psoriasis

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Subjects Rated a "Treatment Success" Based on the	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	Day 15

Investigator s Global Assessment (IGA)	"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).	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
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
Proportion of Subjects With IGA "Treatment Success"	"Treatment success" and IGA as defined in the primary outcome measure.	Day 8
Proportion of Subjects Rated a "Treatment Success" for Each of the Clinical Signs of Psoriasis (Scaling,	"Treatment success" and clinical signs as defined in the secondary outcome measure.	Day 8

Erythema and Plaque Elevation)		
Change From Baseline in Pruritus Score	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).	Day 15
Change in % Body Surface Area (BSA) With Active Psoriasis	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 8 and Day 15

Collaborators and Investigators

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

Sponsor

Therapeutics, Inc.

Collaborators

No information provided

Investigators

- Study Director: Anthony Andrasfay, 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
2015-02-13

First Submitted that Met QC Criteria
2015-02-13

First Posted (Estimated)
2015-02-20

Results Reporting Dates

Results First Submitted
2018-08-30

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

Results First Posted
2018-09-27

Study Record Updates

Last Update Submitted that met QC Criteria
2018-10-11

Last Update Posted
2018-11-08

Last Verified
2018-10

More Information

Terms related to this study

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis

Study Documents

No study documents available

ClinicalTrials.gov return to the CTG homepage

Go to the classic website

Record 1 of 1

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

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

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

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

COMPLETED

A Study of Safety and Effectiveness of Ustekinumab (CNTO 1275) in Patients With Moderate to Severe Plaque-type Psoriasis (PHOENIX1)

ClinicalTrials.gov ID NCT00267969

Sponsor Centocor Research & Development, Inc.

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

Last Update Posted 2013 06 17

Study Details Tab

Study Overview

Brief Summary

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

Feedback

Detailed Description

This is a randomized (patients are assigned to different treatments based on chance), double blind (neither the patient nor the physician knows whether medication or placebo [an inactive substance that is compared with a medication to test whether the medication has a real effect in a clinical study] is being taken, or at what dosage), parallel group (each group of patients are treated at the same time), multicenter study to determine the effectiveness and safety of two different doses of ustekinumab administered subcutaneously (under the skin) as compared with placebo in patients with moderate to severe plaque type psoriasis (the most common type of psoriasis). 766 patients will be randomized to Group 1 (ustekinumab 45 mg), Group 2 (ustekinumab 90 mg) and Group 3 (placebo) at Week 0. The study was designed to evaluate the effectiveness and safety of 2 dose regimens of ustekinumab: (1) 45 mg at Weeks 0 and 4 followed by 45 mg every 12 weeks maintenance therapy (treatment designed to help the original primary treatment succeed) and (2) 90 mg at Weeks 0 and 4 followed by 90 mg every 12 weeks maintenance therapy. The study will consist of 4 periods: (1) Placebo controlled portion of study [Week 0 to Week 12] during which the safety and effectiveness of 2 doses (45mg and 90mg) of ustekinumab will be compared to placebo; (2) Placebo crossover and active treatment portion of study [Week 12 to Week 40] during which patients randomized to receive placebo at Week 0 will crossover to receive ustekinumab, and all patients will receive active treatment; (3) Randomized withdrawal portion of study [beginning at Week 40] during which patients who received ustekinumab [45mg or 90mg every 12 weeks] at Week 0 and are responding to it, will be randomized either to placebo or continued maintenance therapy with ustekinumab; and (4) Long term extension [from Week 52 to Week 264 (ie, 5 years)] period during which the safety and effectiveness of ustekinumab long term use will be evaluated in patients.

Official Title

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

Conditions

Psoriasis

Intervention / Treatment

- Drug: ustekinumab
- Drug: placebo

Other Study ID Numbers

- CR006328
- C0743T08 (Other Identifier) (OTHER: Centocor Research & Development, Inc., PA, USA)
- 2005 003529 15 (EudraCT Number)

Study Start

2005 12

Primary Completion (Actual)

2006 07

Study Completion (Actual)

2011 05

Enrollment (Actual)

766

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

Arizona Locations

Phoenix, Arizona, United States

Click to view interactive map

California Locations

- Los Angeles, California, United States
- Redwood City, California, United States
- Santa Monica, 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:

- Patients with plaque type psoriasis diagnosed at least 6 months prior and covering at least 10% of total body surface areas
- Have psoriasis area and severity index score of >=12
- Patients who are considered by treating dermatologist to be a candidate for phototherapy or systemic treatment of psoriasis
- Have no history of latent or active TB

Exclusion Criteria:

- Currently have nonplaque forms of psoriasis or drug induced psoriasis
- Have any therapeutic agent targeted at reducing IL 12 or IL 23
- Have had a BCG vaccination within the previous 12 months
- 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
- Have or ever have had a nontuberculous mycobacterial infection or opportunistic infection
- Patients known to be infected with human immunodeficiency virus, hepatitis B, or hepatitis C
- 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)

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: ustekinumab 45 mg Patients received ustekinumab 45 mg at Weeks 0, 4 and 16. Treatments after Week 16 were dependent on clinical response. At Week 40, patients who achieved PASI 75 at both Week 28 and Week 40 were re-randomized to withdraw from therapy (placebo) or continue 45 mg every 12 week maintenance therapy.	Drug: ustekinumab • Type = exact number, Form = solution for injection, Number = 45 and 90, Unit = mg, Route = subcutaneous (SC) administered at Weeks 0, 4 and 16. Both treatments (45 mg and 90 mg) administered every 12 weeks after Week 16 depending on clinical response. • Other Names: ◦ CNTO 1275
Experimental: ustekinumab 90 mg Patients received ustekinumab 90 mg at Week 0, 4 and 16. Treatments after Week 16 were dependent on clinical response. At Week 40, patients who achieved PASI 75 at both Week 28 and Week 40 were re-randomized to withdraw from therapy (placebo) or continue	Drug: ustekinumab • Type = exact number, Form = solution for injection, Number = 45 and 90, Unit = mg, Route = subcutaneous (SC) administered at Weeks 0, 4 and 16. Both treatments (45 mg and 90 mg) administered every 12 weeks after Week 16 depending on clinical response. • Other Names: ◦ CNTO 1275

90 mg every 12 week maintenance therapy.	
Placebo Comparator: Placebo Patients received placebo at Weeks 0 and 4. At Weeks 12 and 16, placebo crossed over to receive ustekinumab 45 mg or 90 mg. Treatments after Week 16 were dependent on clinical response.	Drug: placebo • Form = solution for injection, route = SC administered at Weeks 0 and 4. At Weeks 12 and 16, placebo will be crossed over to receive ustekinumab 45 mg or 90 mg.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Psoriasis Area-and-severity Index (PASI) 75% Improvement From Baseline at Week 12.	The number of participants achieving at least 75% improvement from baseline in Psoriasis Area and Severity Index (PASI) (0 [best] - 72 [worst]) at Week 12. This is a test of how bad a person s psoriasis is. The combination of redness, scaling, and thickness, as well as overall body involvement determine the PASI score.	Week 12

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants Who Achieved a	The PGA is used to determine the participant s psoriasis lesions overall at a given time point. Overall lesions will be graded as : (0) = cleared,	Week 12

Physician Global Assessment (PGA) Score of Cleared (0) or Minimal (1) at Week 12	(1) = minimal, (2) = mild, (3) = moderate, (4) = marked, and (5) = severe for induration, erythema, and scaling. The sum of the 3 scales will be divided by 3 to obtain a final PGA score ranging from 0 [best] to 5 [worst].	
Change From Baseline in Dermatology Life Quality Index (DLQI) at Week 12	Change from baseline in Dermatology Life Quality Index (DLQI) from baseline at Week 12. This 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 0 (no impairment in quality of life) to 30 (most impairment in quality of life).	Baseline (Week 0), Week 12
Psoriasis Area and Severity Index (PASI) 75 Responders at Week 52	The number of participants achieving at least 75% improvement from baseline in Psoriasis Area and Severity Index (PASI) (0 [best] - 72 [worst]) at Week 52 in participants randomly assigned to a treatment group at Week 40. This is a test of how bad a persons psoriasis is. The combination of redness, scaling, and thickness, as well as overall body involvement determine the PASI score.	Week 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 Research & Development, Inc. Clinical Trial, Centocor Research & Development, 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
2005-12-20

First Submitted that Met QC Criteria
2005-12-20

First Posted (Estimated)
2005-12-22

Results Reporting Dates

Results First Submitted
2009-10-23

Results First Submitted that Met QC Criteria
2012-07-23

Results First Posted (Estimated)
2012-08-24

Study Record Updates

Last Update Submitted that met QC Criteria
2013-06-10

Last Update Posted (Estimated)
2013-06-17

Last Verified
2013-06

More Information

Terms related to this study

Keywords Provided by Centocor Research & Development, Inc.

Ustekinumab
CNTO1275
Plaque type Psoriasis
Interleukin 23
IL 23
Psoriasis
Interleukin 12
IL 12

Additional Relevant MeSH Terms

Skin Diseases, Papulosquamous
Skin Diseases
Psoriasis
Dermatologic Agents
Ustekinumab

Study Documents

No study documents available

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

Go to the c ass c webs te

Record 1 of 1

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

Read our fu d sc a mer (https //c n ca tr a s gov/about s te/d sc a mer) for deta s

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

Multiple Dose Escalation Study In Medically Stable Subjects With Psoriasis

ClinicalTrials.gov ID NCT01736696

Sponsor Pfizer

Information provided by Pfizer (Respons b e Party)

Last Update Posted 2013 02 20

Study Details Tab

Study Overview

Brief Summary

Th s study was conducted n subjects w th psor as s to eva uate drug act v ty n th s pat ent popu at on by ana ys s of changes n psor at c es on b opsy character st cs Th s subject popu at on was se ected to eva uate potent a y re evant b o og ca act v ty of CP 690,550 as we as assess ng safety and pharmacok net cs

Official Title

Phase 1, nvest gator B nd, Subject B nd, Sponsor Open, P acebo Contro ed, Two Week, Mu t p e Dose Esca at on Study n Med ca y Stab e Subjects W th Psor as s To Eva uate The Safety, To erab ty, Pharmacok net cs And Pharmacodynam cs Of CP 690,550

Conditions

Psor as s mmunomodu at on

Intervention / Treatment

- Drug tofac t n b
- Drug tofac t n b
- Drug tofac t n b
- Drug tofac t n b
- Drug tofac t n b
- Drug tofac t n b

Other Study ID Numbers

- A3921003

Feedback

Study Start

2002 11

Primary Completion (Actual)

2004 04

Study Completion (Actual)

2004 04

Enrollment (Actual)

59

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

United States

Arkansas Locations

Little Rock, Arkansas, United States, 72202
Pfizer nves iga ional Si e

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

- Ma e and/or fema e subjects between the ages of 18 and 65 years, nc us ve, w th act ve psor as s es on(s)
- Subjects shou d be hea thy w th the except on of psor as s, where 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 B ood pressure must be < 140/89 Body Mass ndex (BM) between 18 36 kg/m2, nc us ve; and a tota body we ght >50 kg (110 bs)
- The fo ow ng aboratory var ab es must be no more than 10% be ow the ower m t of the norma reference range RBC, hemog ob n, hematocr t, WBC, abso ute neutroph count The abso ute ymphocyte count must be greater than or equa to the ower m t of the reference range Va ues for AST, ALT, b rub n and a ka ne phosphatase must be no more than 10% above the upper m t of the norma reference range Va ues for tota cho estero and LDL must be no more than 20% above the upper m t of the norma reference range except for subjects be ng treated for hyper p dem a Norma g omeru ar fi trat on rate (> 80 mL/m n)

Exc us on Cr ter a

- Subjects w th ev dence or h story of c n ca y s gn ficant hemato og ca , rena , uro og ca , endocr ne, pu monary, gastro ntest na , card ovascu ar, hepat c, psych atr c, neuro og c d sorder
- Subjects w th contro ed essent a hypertens on and/or hyper p dem a may be e g b e for the study prov ded that any med cat ons that are adm n stered
- Screen ng 12 ead ECG demonstrat ng at east one of the fo ow ng heart rate > 100 bpm, QRS >120 msec, QTc > 430 msec (ma es), QTc > 450 msec (fema es) or PR > 220 msec
- Abnorma chest rad ographs nc ud ng, but not m ted to, ev dence of past or present tubercu os s nfect on H story of tubercu os s w thout treatment and/or pos t ve tubercu n react on w thout known vacc nat on w th BCG
- Subjects w th a h story of tumors w th the except on of adequate y treated basa ce carc noma of the sk n

Ages Eligible for Study

18 Years to 65 Years (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 : Tr p e (Part c pant, Care Prov der, nvest gator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Exper menta 5 mg B D 5 mg B D for 13 days and once on Day 14	Drug tofac t n b • 5 mg B D For 13 days and once on Day 14
Exper menta 10 mg B D 10 mg B D for13 days and once on Day 14*	Drug tofac t n b • 10 mg B D for 13 days and once on Day 14*
Exper menta 20 mg B D 20 mg B D for 13 days and once on Day 14	Drug tofac t n b • 20 mg B D for 13 days and once on Day 14
Exper menta 30 mg B D 30 mg B D for 13 days and once on Day 14	Drug tofac t n b • 30 mg B D for 13 days and once on Day 14
Exper menta 60 mg QD 60 mg QD for 14 days	Drug tofac t n b • 60 mg tab et once a day (QD) for 14 days
Exper menta 50 mg B D 50 mg B D x 13 days and once on day 14	Drug tofac t n b • 50 mg tab ets two t mes a day (B D) for 13 days and once on day 14

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change From Base ne n QT nterva at 1 Hour Post Morn ng Dose (HPD 1) on Day 1	Tr p cate 12- ead e ectrocard ogram (ECG) measurements (each record ng separated by approx mate y 2 m nutes) were performed and average was ca cu ated QT nterva The t me correspond ng to the beg nn ng of depo ar zat on to repo ar zat on of the ventr c es For each schedu ed hour post morn ng dose (HPD), except for HPD=0, the t me-matched base ne QT was defined as the mean of the tr p cates on Day 0 at the same nom na HPD	23 hours (hrs) pr or to morn ng dose on Day 1 (Base ne for HPD 1), 1 hour (hr) post morn ng dose on Day 1
Change From Base ne n QT nterva at 2 Hour Post Morn ng Dose (HPD 2) on Day 1	Tr p cate 12- ead ECG measurements (each record ng separated by approx mate y 2 m nutes) were performed and average was ca cu ated QT nterva The t me correspond ng to the beg nn ng of depo ar zat on to repo ar zat on of the ventr c es For each schedu ed hour post morn ng dose (HPD), except for HPD=0, the t me-matched base ne QT was defined as the mean of the tr p cates on Day 0 at the same nom na HPD	22 hrs pr or to morn ng dose on Day 1 (Base ne for HPD 2), 2 hrs post morn ng dose on Day 1

Change From Base ne n QT nterva at 4 Hour Post Morn ng Dose (HPD 4) on Day 1	Tr p cate 12- ead ECG measurements (each record ng separated by approx mate y 2 m nutes) were performed and average was ca cu ated QT nterva The t me correspond ng to the beg nn ng of depo ar zat on to repo ar zat on of the ventr c es For each schedu ed HPD, except for HPD=0, the t me-matched base ne QT was defined as the mean of the tr p cates on Day 0 at the same nom na HPD	20 hrs pr or to morn ng dose on Day 1 (Base ne for HPD 4), 4 hrs post morn ng dose on Day 1
Change From Base ne n QT nterva at 8 Hour Post Morn ng Dose (HPD 8) on Day 1	Tr p cate 12- ead ECG measurements (each record ng separated by approx mate y 2 m nutes) were performed and average was ca cu ated QT nterva The t me correspond ng to the beg nn ng of depo ar zat on to repo ar zat on of the ventr c es For each schedu ed HPD, except for HPD=0, the t me-matched base ne QT was defined as the mean of the tr p cates on Day 0 at the same nom na HPD	16 hrs pr or to morn ng dose on Day 1 (Base ne for HPD 8), 8 hrs post morn ng dose on Day 1
Change From Base ne n QT nterva at 12 Hour Post Morn ng Dose (HPD 12) on Day 1	Tr p cate 12- ead ECG measurements (each record ng separated by approx mate y 2 m nutes) were performed and average was ca cu ated QT nterva The t me correspond ng to the beg nn ng of depo ar zat on to repo ar zat on of the ventr c es For each schedu ed HPD, except for HPD=0, the t me-matched base ne QT was defined as the mean of the tr p cates on Day 0 at the same nom na HPD	12 hrs pr or to morn ng dose on Day 1 (Base ne for HPD 12), 12 hrs post morn ng dose on Day 1
Change From Base ne n QT nterva at 16 Hour Post Morn ng Dose (HPD 16) on Day 1	Tr p cate 12- ead ECG measurements (each record ng separated by approx mate y 2 m nutes) were performed and average was ca cu ated QT nterva The t me correspond ng to the beg nn ng of depo ar zat on to repo ar zat on of the ventr c es For each schedu ed HPD, except for HPD=0, the t me-matched base ne QT was defined as the mean of the tr p cates on Day 0 at the same nom na HPD Change from base ne n QT nterva at HPD 16 was p anned to be ana yzed for part c pants who rece ved CP-690,550 60 mg and match ng p acebo	8 hrs pr or to morn ng dose on Day 1 (Base ne for HPD 16), 16 hrs post morn ng dose on Day 1
Change From Base ne n QT nterva at 0 Hour Post Morn ng Dose (HPD 0) on Day 14	Tr p cate 12- ead ECG measurements (each record ng separated by approx mate y 2 m nutes) were performed and average was ca cu ated QT nterva The t me correspond ng to the beg nn ng of depo ar zat on to repo ar zat on of the ventr c es The mean of the tr p cates at HPD=0 on Day 1 w be defined as the base ne for HPD=0	Hour 0 (pre-dose) on Day 1 (Base ne for HPD 0), 0 hr on Day 14
Change From Base ne n QT nterva at 1 Hour Post Morn ng Dose (HPD 1) on Day 14	Tr p cate 12- ead ECG measurements (each record ng separated by approx mate y 2 m nutes) were performed and average was ca cu ated QT nterva The t me correspond ng to the beg nn ng of depo ar zat on to repo ar zat on of the ventr c es For each schedu ed HPD, except for HPD=0, the t me-matched base ne QT was defined as the mean of the tr p cates on Day 0 at the same nom na HPD	23 hrs pr or to morn ng dose on Day 1 (Base ne for HPD 1), 1 hr post morn ng dose on Day 14
Change From Base ne n QT nterva at 2 Hour Post Morn ng Dose (HPD 2) on Day 14	Tr p cate 12- ead ECG measurements (each record ng separated by approx mate y 2 m nutes) were performed and average was ca cu ated QT nterva The t me correspond ng to the beg nn ng of depo ar zat on to repo ar zat on of the ventr c es For each schedu ed HPD, except for HPD=0, the t me-matched base ne QT was defined as the mean of the tr p cates on Day 0 at the same nom na HPD	22 hrs pr or to morn ng dose on Day 1 (Base ne for HPD 2), 2 hrs post morn ng dose on Day 14

Change From Base ne n QT nterva at 4 Hour Post Morn ng Dose (HPD 4) on Day 14	Tr p cate 12- ead ECG measurements (each record ng separated by approx mate y 2 m nutes) were performed and average was ca cu ated QT nterva The t me correspond ng to the beg nn ng of depo ar zat on to repo ar zat on of the ventr c es For each schedu ed HPD, except for HPD=0, the t me-matched base ne QT was defined as the mean of the tr p cates on Day 0 at the same nom na HPD	20 hrs pr or to morn ng dose on Day 1 (Base ne for HPD 4), 4 hrs post morn ng dose on Day 14
Change From Base ne n QT nterva at 8 Hour Post Morn ng Dose (HPD 8) on Day 14	Tr p cate 12- ead ECG measurements (each record ng separated by approx mate y 2 m nutes) were performed and average was ca cu ated QT nterva The t me correspond ng to the beg nn ng of depo ar zat on to repo ar zat on of the ventr c es For each schedu ed HPD, except for HPD=0, the t me-matched base ne QT was defined as the mean of the tr p cates on Day 0 at the same nom na HPD	16 hrs pr or to morn ng dose on Day 1 (Base ne for HPD 8), 8 hrs post morn ng dose on Day 14
Change From Base ne n QT nterva at 12 Hour Post Morn ng Dose (HPD 12) on Day 14	Tr p cate 12- ead ECG measurements (each record ng separated by approx mate y 2 m nutes) were performed and average was ca cu ated QT nterva The t me correspond ng to the beg nn ng of depo ar zat on to repo ar zat on of the ventr c es For each schedu ed HPD, except for HPD=0, the t me-matched base ne QT was defined as the mean of the tr p cates on Day 0 at the same nom na HPD	12 hrs pr or to morn ng dose on Day 1 (Base ne for HPD 12), 12 hrs post morn ng dose on Day 14
Number of Part c pants W th ncrease From Base ne n Corrected QT (QTc) nterva	Tr p cate 12- ead ECG measurements (each record ng separated by approx mate y 2 m nutes) were performed and average was ca cu ated The t me correspond ng to beg nn ng of depo ar zat on to repo ar zat on of the ventr c es (QT nterva) was adjusted for RR nterva us ng QT and RR from each ECG by Fr der c a's formu a (QTcF = QT d v ded by cube root of RR) and by Bazette's formu a (QTcB = QT d v ded by square root of RR) Part c pants w th max mum ncrease from base ne of 30 to ess than (<) 60 msec(border ne) and greater than or equa to (>=) 60 msec (pro onged) were summar zed	1, 2, 4, 8, 12 hrs post dose, add t ona 16 hrs post dose for 60 mg once da y group on Day 1; 1, 2 hrs post dose on Day 4, 7, 10;1,2,4,8,12 hrs post dose on Day 14; Day 21
Number of Part c pants W th Corrected QT (QTc) nterva Greater Than or Equa to 500 M second	Tr p cate 12- ead ECG measurements (each record ng separated by approx mate y 2 m nutes) were performed and average was ca cu ated The t me correspond ng to beg nn ng of depo ar zat on to repo ar zat on of the ventr c es (QT nterva) was adjusted for RR nterva us ng QT and RR from each ECG by Fr der c a's formu a (QTcF = QT d v ded by cube root of RR) and by Bazette's formu a (QTcB = QT d v ded by square root of RR) Part c pants w th max mum QTc >=500 msec were reported	1, 2, 4, 8, 12 hrs post dose, add t ona 16 hrs post dose for 60 mg once da y group on Day 1; 1, 2 hrs post dose on Day 4, 7, 10;1,2,4,8,12 hrs post dose on Day 14; Day 21
Area Under the Curve From T me Zero to End of Dos ng nterva (AUCtau) at Day 1	AUCtau = area under the curve from t me zero to end of dos ng nterva	0 (pre-dose), 0 25, 0 5, 1, 2, 3, 4, 8, 12 hrs

		post dose on Day 1
Area Under the Curve From T me Zero to End of Dos ng nterva (AUCtau) at Day 14	AUCtau = area under the curve from t me zero to end of dos ng nterva	0 (pre-dose), 0 25, 0 5, 1, 2, 3, 4, 8, 12 hrs post dose on Day 14
Max mum Observed P asma Concentrat on (Cmax) at Day 1		0 (pre-dose), 0 25, 0 5, 1, 2, 3, 4, 8, 12 hrs post dose on Day 1
Max mum Observed P asma Concentrat on (Cmax) at Day 14		0 (pre-dose), 0 25, 0 5, 1, 2, 3, 4, 8, 12 hrs post dose on Day 14
T me to Reach Max mum Observed P asma Concentrat on (Tmax) at Day 1		0 (pre-dose), 0 25, 0 5, 1, 2, 3, 4, 8, 12 hrs post dose on Day 1
T me to Reach Max mum Observed P asma Concentrat on (Tmax) at Day 14		0 (pre-dose), 0 25, 0 5, 1, 2, 3, 4, 8, 12 hrs post dose on Day 14
Accumu at on Rat o (R0)	Accumu at on rat o was ca cu ated as, R0 = area under the curve from t me zero to end of dos ng nterva (AUCtau) on Day 14 d v ded by area under the curve from t me zero to end of dos ng nterva (AUCtau) on Day 1	0 (pre-dose), 0 25, 0 5, 1, 2, 3, 4, 8, 12 hrs post dose on Day 1 and Day 14
Percent Change From Base ne n F uorescence-Act vated Ce Sort ng (FACS) Ana ys s at Day 1	Abso ute ce counts of c uster of d fferent at on 3 (CD3) T ymphocytes, c uster of d fferent at on 4 (CD4) He per/ nducer T- Lymphocytes react ve w th Major H stocompatab ty Comp ex- (MHC-), and c uster of d fferent at on 8 (CD8) Suppressor/Cytotox c T- ymphocyte react ve w th Major H stocompatab ty Comp ex- (MHC-), c uster of d fferent at on 16/56 (CD16/56) natura k er Ce s, c uster of d fferent at on 19 (CD19) B-Lymphocytes determ ned us ng FACS Base ne defined as mean of samp es co ected dur ng screen ng, v s t n wh ch b opsy was taken, at Day 0 and at 0 hour Day 1	Base ne, 1 hr post-dose on Day 1
Percent Change From Base ne n F uorescence-Act vated Ce Sort ng (FACS) Ana ys s at Day 2	Abso ute ce counts of c uster of d fferent at on 3 (CD3) T ymphocytes, c uster of d fferent at on 4 (CD4) He per/ nducer T- Lymphocytes react ve w th Major H stocompatab ty Comp ex- (MHC-), and c uster of d fferent at on 8 (CD8) Suppressor/Cytotox c T- ymphocyte react ve w th Major H stocompatab ty Comp ex- (MHC-), c uster of d fferent at on 16/56 (CD16/56) natura k er Ce s, c uster of d fferent at on 19 (CD19) B-Lymphocytes determ ned us ng FACS Base ne defined as mean of samp es	Base ne, hr 0 on Day 2

	co ected dur ng screen ng, v s t n wh ch b opsy was taken, at Day 0 and at 0 hour Day 1	
Percent Change From Base ne n F uorescence-Act vated Ce Sort ng (FACS) Ana ys s at Day 4	Abso ute ce counts of c uster of d fferent at on 3 (CD3) T ymphocytes, c uster of d fferent at on 4 (CD4) He per/ nducer T- Lymphocytes react ve w th Major H stocompatab ty Comp ex- (MHC-), and c uster of d fferent at on 8 (CD8) Suppressor/Cytotox c T- ymphocyte react ve w th Major H stocompatab ty Comp ex- (MHC-), c uster of d fferent at on 16/56 (CD16/56) natura k er Ce s, c uster of d fferent at on 19 (CD19) B-Lymphocytes determ ned us ng FACS Base ne defined as mean of samp es co ected dur ng screen ng, v s t n wh ch b opsy was taken, at Day 0 and at 0 hour Day 1	Base ne, hr 0 on Day 4
Percent Change From Base ne n F uorescence-Act vated Ce Sort ng (FACS) Ana ys s at Day 7	Abso ute ce counts of c uster of d fferent at on 3 (CD3) T ymphocytes, c uster of d fferent at on 4 (CD4) He per/ nducer T- Lymphocytes react ve w th Major H stocompatab ty Comp ex- (MHC-), and c uster of d fferent at on 8 (CD8) Suppressor/Cytotox c T- ymphocyte react ve w th Major H stocompatab ty Comp ex- (MHC-), c uster of d fferent at on 16/56 (CD16/56) natura k er Ce s, c uster of d fferent at on 19 (CD19) B-Lymphocytes determ ned us ng FACS Base ne defined as mean of samp es co ected dur ng screen ng, v s t n wh ch b opsy was taken, at Day 0 and at 0 hour Day 1	Base ne, hr 0 on Day 7
Percent Change From Base ne n F uorescence-Act vated Ce Sort ng (FACS) Ana ys s at Day 10	Abso ute ce counts of c uster of d fferent at on 3 (CD3) T ymphocytes, c uster of d fferent at on 4 (CD4) He per/ nducer T- Lymphocytes react ve w th Major H stocompatab ty Comp ex- (MHC-), and c uster of d fferent at on 8 (CD8) Suppressor/Cytotox c T- ymphocyte react ve w th Major H stocompatab ty Comp ex- (MHC-), c uster of d fferent at on 16/56 (CD16/56) natura k er Ce s, c uster of d fferent at on 19 (CD19) B-Lymphocytes determ ned us ng FACS Base ne defined as mean of samp es co ected dur ng screen ng, v s t n wh ch b opsy was taken, at Day 0 and at 0 hour Day 1	Base ne, hr 0 on Day 10
Percent Change From Base ne n F uorescence-Act vated Ce Sort ng (FACS) Ana ys s at Day 14	Abso ute ce counts of c uster of d fferent at on 3 (CD3) T ymphocytes, c uster of d fferent at on 4 (CD4) He per/ nducer T- Lymphocytes react ve w th Major H stocompatab ty Comp ex- (MHC-), and c uster of d fferent at on 8 (CD8) Suppressor/Cytotox c T- ymphocyte react ve w th Major H stocompatab ty Comp ex- (MHC-), c uster of d fferent at on 16/56 (CD16/56) natura k er Ce s, c uster of d fferent at on 19 (CD19) B-Lymphocytes determ ned us ng FACS Base ne defined as mean of samp es co ected dur ng screen ng, v s t n wh ch b opsy was taken, at Day 0 and at 0 hour Day 1	Base ne; hr 0, 8 hr post-dose on Day 14
Percent Change From Base ne n F uorescence-Act vated Ce Sort ng (FACS) Ana ys s at Day 18	Abso ute ce counts of c uster of d fferent at on 3 (CD3) T ymphocytes, c uster of d fferent at on 4 (CD4) He per/ nducer T- Lymphocytes react ve w th Major H stocompatab ty Comp ex- (MHC-), and c uster of d fferent at on 8 (CD8) Suppressor/Cytotox c T- ymphocyte react ve w th Major H stocompatab ty Comp ex- (MHC-), c uster of d fferent at on 16/56 (CD16/56) natura k er Ce s, c uster of d fferent at on 19 (CD19) B-Lymphocytes determ ned us ng FACS Base ne defined as mean of samp es co ected dur ng screen ng, v s t n wh ch b opsy was taken, at Day 0 and at 0 hour Day 1	Base ne, Hour 0 on Day 18

Percent Change From Base ne n F uorescence-Act vated Ce Sort ng (FACS) Ana ys s at Day 21	Abso ute ce counts of c uster of d fferent at on 3 (CD3) T ymphocytes, c uster of d fferent at on 4 (CD4) He per/ nducer T- Lymphocytes react ve w th Major H stocompatab ty Comp ex- (MHC-), and c uster of d fferent at on 8 (CD8) Suppressor/Cytotox c T- ymphocyte react ve w th Major H stocompatab ty Comp ex- (MHC-), c uster of d fferent at on 16/56 (CD16/56) natura k er Ce s, c uster of d fferent at on 19 (CD19) B-Lymphocytes determ ned us ng FACS Base ne defined as mean of samp es co ected dur ng screen ng, v s t n wh ch b opsy was taken, at Day 0 and at 0 hour Day 1	Base ne, hr 0 on Day 21
Percent Change From Base ne n F uorescence-Act vated Ce Sort ng (FACS) Ana ys s at Day 28	Abso ute ce counts of c uster of d fferent at on 3 (CD3) T ymphocytes, c uster of d fferent at on 4 (CD4) He per/ nducer T- Lymphocytes react ve w th Major H stocompatab ty Comp ex- (MHC-), and c uster of d fferent at on 8 (CD8) Suppressor/Cytotox c T- ymphocyte react ve w th Major H stocompatab ty Comp ex- (MHC-), c uster of d fferent at on 16/56 (CD16/56) natura k er Ce s, c uster of d fferent at on 19 (CD19) B-Lymphocytes determ ned us ng FACS Base ne defined as mean of samp es co ected dur ng screen ng, v s t n wh ch b opsy was taken, at Day 0 and at 0 hour Day 1	Base ne, hr 0 on Day 28
Percent Change From Base ne n F uorescence-Act vated Ce Sort ng (FACS) Ana ys s at Day 42	Abso ute ce counts of c uster of d fferent at on 3 (CD3) T ymphocytes, c uster of d fferent at on 4 (CD4) He per/ nducer T- Lymphocytes react ve w th Major H stocompatab ty Comp ex- (MHC-), and c uster of d fferent at on 8 (CD8) Suppressor/Cytotox c T- ymphocyte react ve w th Major H stocompatab ty Comp ex- (MHC-), c uster of d fferent at on 16/56 (CD16/56) natura k er Ce s, c uster of d fferent at on 19 (CD19) B-Lymphocytes determ ned us ng FACS Base ne defined as mean of samp es co ected dur ng screen ng, v s t n wh ch b opsy was taken, at Day 0 and at 0 hour Day 1	Base ne, hr 0 on Day 42
Change From Base ne n mmune Ce Funct on at Day 14	The degree of mmunosuppress on nduced by the study drug adm n strat on was eva uated us ng a b o um nescent assay n wh ch the concentrat on of Adenos ne-5-Tr phosphate (ATP) re eased by CD4 ce s was measured ATP concentrat ons re eased from st mu ated and unst mu ated ce s were eva uated ATP Concentrat on ess than or equa to (<=) 225 ow mmune ce response, 226 to 524 Moderate mmune ce response, >= 525 strong mmune ce response Base ne was defined as the mean of the samp es co ected dur ng the pre-dose b opsy	Base ne (W th n 7 days pr or to Day 1), Day 14
Change From Base ne n Ret cu ocyte Count at Day 2	Ret cu ocyte count was assessed to detect potent a of Janus k nase 2 (JAK2) med ated erythropo es s	Base ne (W th n 7 days pr or to Day 1), Day 2
Change From Base ne n Ret cu ocyte Count at Day 4	Ret cu ocyte count was assessed to detect potent a of Janus k nase 2 (JAK2) med ated erythropo es s	Base ne (W th n 7 days pr or to Day 1), Day 4
Change From Base ne n Ret cu ocyte Count at Day 7	Ret cu ocyte count was assessed to detect potent a of Janus k nase 2 (JAK2) med ated erythropo es s	Base ne (W th n 7 days pr or to Day 1), Day 7
Change From Base ne n Ret cu ocyte Count at Day	Ret cu ocyte count was assessed to detect potent a of Janus k nase 2 (JAK2) med ated erythropo es s	Base ne (W th n 7 days

10		pr or to Day 1), Day 10
Change From Base ne n Ret cu ocyte Count at Day 15	Ret cu ocyte count was assessed to detect potent a of Janus k nase 2 (JAK2) med ated erythropo es s	Base ne (W th n 7 days pr or to Day 1), Day 15
Change From Base ne n Ret cu ocyte Count at Day 21	Ret cu ocyte count was assessed to detect potent a of Janus k nase 2 (JAK2) med ated erythropo es s	Base ne (W th n 7 days pr or to Day 1), Day 21
Change From Base ne n Ret cu ocyte Count at Day 28	Ret cu ocyte count was assessed to detect potent a of Janus k nase 2 (JAK2) med ated erythropo es s	Base ne (W th n 7 days pr or to Day 1), Day 28
Change From Base ne n Ret cu ocyte Count at Day 42	Ret cu ocyte count was assessed to detect potent a of Janus k nase 2 (JAK2) med ated erythropo es s	Base ne (W th n 7 days pr or to Day 1), Day 42
T me to Reach Max mum Change From Base ne and T me to Return to Base ne Va ue for F uorescence-Act vated Ce Sort ng (FACS), Ret cu ocyte Counts and mmune Ce Funct on		Day 0 (pre-dose), 1, 2, 4, 7, 10, 14, 15, 18, 21, 28, 42
Ha f Max ma Effect ve Area Under the Concentrat on-T me Curve 50 (EAUC 50)	EAUC 50 was ca cu ated from a regress on ana yses us ng area under the concentrat on-t me curve (AUC) as the ndependent var ab e A s gmo d max mum effect (Emax) mode was used to exp a n the re at onsh p between AUC and mod fied Psor as s Sever ty ndex (mPAS) score, where Emax was the max mum effect (100 percent reduct on n the tota mPAS score from base ne), and EAUC 50 was the AUC where 50 percent of the max mum effect was measured	Day 14

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Part c pants W th Mod fied Psor as s Sever ty ndex (mPAS) at Day 14	Mod fied Psor as s Area and Sever ty ndex (mPAS) assessed es on sever ty but not the body surface area affected Sever ty was est mated by c n ca s gns of erythema, ndurat on, sca ng; ranged 0-4 0=none, 1=s ght, 2=moderate, 3=marked, 4=very marked F na mPAS = sum of the each component scores Tota score range 0-12 , h gher score nd cated more sever ty	Base ne (W th n 7 days pr or to Day 1) up to Day 14
Number of Part c pants W th Phys c an's G oba Assessment (PGA) of Psor as s	Phys c an g oba assessment (PGA) of Psor as s s a 7-po nt sca e used to assess sever ty of psor at c p aques, sca ng and/or erythema Sever ty sca e ranged from 1 to 7 1=severe, 2=moderate to severe, 3=moderate, 4=m d to moderate, 5=m d, 6=a most c ear, 7=c ear (no s gn of psor as s)	Base ne (W th n 7 days pr or to Day 1) up to Day 14

Gene Express on n Psor at c P aque B ops es	Gene express on by quant tat ve po ymer zed cha n react on (PCR) us ng standard curve (SC) method generated by near regress on us ng og thresho d cyc e versus og(ce number) Kerat n (K)-16, nduc b e n tr c ox de synthase (NOS), nter euk n 8 (L-8), CD25, Granzyme B, L-2, L-7, L-15, nterferon-gamma (NF-gamma), C-X-C mot f chemok ne(CXCL10), perfor n 1, B-ce Lymphoma 2 (BCL-2), BCL2 assoc ated X Prote n (BAX), Tumor Necros s Factor Fas L gand (TNF-FasL), and pro ferat ng ce nuc ear ant gen (PCNA) presented as contro gene norma zed express on (re at ve express on) w th n SC	Day 14
mmunoh stochem stry From Psor at c P aque B ops es	mmunoh stochem ca sta n ng of sk n b ops es was performed w th monoc ona ant bod es d rected aga nst c uster of d fferent at on 3 (CD3) and c uster of d fferent at on 8 (CD8) T- ymphocytes, c uster of d fferent at on 16/56 (CD16/56) natura k er ce s, and c uster of d fferent at on 83 (CD83) mature dendr t c ce s Base ne was defined as mean of samp es obta ned at the screen ng v s t w th n 7 days pr or to Day 1, at the base ne b opsy, and Day 0 mmunoh stochem stry resu ts were p anned to be ana yzed for part c pants who rece ved CP-690,550 5, 20, 30 mg and match ng p acebo	Base ne (w th n 7 days pr or to Day 1), Day 14
Number of Part c pants W th Kerat n 16 (K16) Express on	mmunoh stochem ca sta n ng of sk n b ops es was performed w th monoc ona ant bod es d rected aga nst K16 Number of part c pants w th K16 express on were assessed qua tat ve y us ng suprabasa kerat nocytes	Base ne (w th n 7 days pr or to Day 1) up to Day 14
Number of Part c pants W th ntrace u ar Adhes on Mo ecu e (CAM-1) by Ep derma Kerat nocytes Express on	mmunoh stochem ca sta n ng of sk n b ops es was performed w th monoc ona ant bod es d rected aga nst CAM-1 Number of part c pants w th CAM-1 express on was to be assessed qua tat ve y us ng ep derma kerat nocytes	Base ne (w th n 7 days pr or to Day 1) up to Day 14
Gene Express on n Per phera B ood	Punch b opsy and serum b ood were assayed for messenger R bonuc e c ac d (mRNA) gene express on by quant tat ve PCR us ng standard curve(SC) method generated by near regress on us ng og thresho d cyc e versus og(ce number) granzyme B, FN-gamma, TNF-a pha (FasL and superfam y member 5 [SF5]), BCL2, BAX, NOS, and CD 25 presented as contro gene norma zed express on(re at ve express on) w th n SC The Re at ve mRNA Gene Express on Leve s re at ve to base ne and norma zed to the housekeep ng gene 18 Svedberg un t r bosoma RNA (18S rRNA)	Day 14

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
2012-11-26

First Submitted that Met QC Criteria
2012-11-26

First Posted (Estimated)
2012-11-29

Results Reporting Dates

Results First Submitted
2012-12-06

Results First Submitted that Met QC Criteria
2013-01-16

Results First Posted (Estimated)
2013-02-20

Study Record Updates

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

Last Update Posted (Estimated)
2013-02-20

Last Verified
2013-01

More Information

Terms related to this study

Keywords Provided by Pfizer

Psor as s
PAS
p aques
sk n b opsy
mmunomodu at on

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
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=A3921003&StudyName=Mu t p e%20Dose%20Esca at on%20Study%20 n%20Med ca y%20Stab e%20Subjects%20W th%20Psor as s%20)