A PHASE 3, MULTI-SITE, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL-GROUP STUDY OF THE EFFICACY AND SAFETY OF 2 ORAL DOSES OF CP-690,550 AND 1 SUBCUTANEOUS DOSE OF ETANERCEPT IN SUBJECTS WITH MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS

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The primary objectives of the study are 1) to compare the efficacy of CP-690,550 (5 mg BID and 10 mg BID) versus etanercept (50 mg BIW) for the reduction in severity of plaque psoriasis after 12 weeks of treatment, and 2) to evaluate the safety and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON38163

Source
ToetsingOnline

Brief title
9002/0045: Psoriasis OPT trails: A3921080

Condition

- Epidermal and dermal conditions

Synonym
Psoriasis, Skin disease with red lesions

Research involving
Human

Sponsors and support

Primary sponsor: Pfizer
Source(s) of monetary or material Support: Pfizer

Intervention

Keyword: 550, CP-690, Etanercept, Phase 3, Psoriasis

Outcome measures

Primary outcome

Physician*s Global Assessment (PGA) response ie, the proportion of subjects achieving a PGA of *clear* or *almost clear*, at Week 12;

Psoriasis Area and Severity Index 75 (PASI75) response ie, the proportion of subjects achieving at least a 75% reduction in Psoriasis Area and Severity Index relative to baseline, at Week 12.

Secondary outcome

PGA response at Week 2, 4, and 8;

Proportion of subjects in each PGA category at various timepoints through Week 12;

PASI75 response at Week 2, 4, and 8;

Actual and change from baseline in PASI and PASI component scores at various timepoints through Week 12;

Proportion of subjects achieving at least a 50% and 90% reduction in PASI relative to baseline (PASI50 and PASI90, respectively) at various timepoints

through Week 12;

Time to PASI50 and PASI75 responses;

Proportion of subjects with a PASI score >=125% of the baseline PASI score at

various timepoints through Week 12;

Actual and change from baseline in the Itch Severity Item (ISI) score at

various timepoints through Week 12;

Actual and change from baseline on the Dermatology Life Quality Index (DLQI)

score at various timepoints through Week 12.

Other patient reported outcome (PRO) measures to be assessed at various

timepoints through Week 12, including:

Short Form-36 (Version 2, Acute) (SF-36);

Patient Global Assessment of Psoriasis (PtGA);

Patient Satisfaction with Study Medication (PSSM);

EuroQol 5 Dimensions (EQ-5D);

Psoriasis Health Care Resource Utilization Questionnaire (Ps-HCRU);

Psoriasis Quality of Life-12 (PQOL-12).

Study description

Background summary

CP-690,550 is being developed for oral treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. CP-690,550 is a potent inhibitor of the Janus Kinase (JAK) family of kinases. While CP-690,550 shows nanomolar inhibitory potency against all JAK family kinases in enzyme studies, it shows functional specificity for JAK1 and JAK1/3 over JAK2 in cell assays. The broad effects of JAK1/3 inhibition on multiple cytokine pathways provides the rationale for developing CP-690,550 as treatment for psoriasis, a disease in which lymphocyte

activation/proliferation plays a pathogenic role. Efficacy of oral dosing with CP-690,550 in psoriasis patients has been demonstrated in 2 studies, a 14-day and a 12-week treatment study, providing clinical support for JAK inhibition as a novel approach to treat plaque psoriasis. This study is a 12-week active comparator study, designed to evaluate the efficacy of CP-690,550 as compared to etanercept and the safety of CP-690,550 for treatment of moderate to severe chronic plaque psoriasis.

Study objective

The primary objectives of the study are 1) to compare the efficacy of CP-690,550 (5 mg BID and 10 mg BID) versus etanercept (50 mg BIW) for the reduction in severity of plaque psoriasis after 12 weeks of treatment, and 2) to evaluate the safety and tolerability of CP-690,550 (5 mg BID and 10 mg BID) in subjects with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy.

Study design

Phase 3, multi-site, randomized, double-blind, double-dummy, placebo-controlled, parallel-group, 12-week study of the efficacy and safety of two oral doses of CP-690,550 (5 mg BID and 10 mg BID) and one subcutaneous dose of etanercept (50 mg BIW) in subjects with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy.

Intervention

Subjects will be randomized in a 3:3:3:1 ratio to one of four parallel treatment groups.
Group A: CP 690,550 5 mg BID oral + Placebo BIW subcutaneous injection
Group B: CP 690,550 10 mg BID oral + Placebo BIW subcutaneous injection
Group C: placebo BID oral + Etanercept 50 mg BIW subcutaneous injection
Group D: placebo BID oral + Placebo BIW subcutaneous injection

Study burden and risks

During a 12 week study period subjects undergo complete and targeted physical examinations, Tb testing, ECG, Chest radiographs, blood and urine collection. Patient reported outcomes are collected using questionnaires.

Contacts

Public

Pfizer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Evidence of a personally signed and dated informed consent document indicating that the subject (or a legally acceptable representative) has been informed of all pertinent aspects of the trial.
2. Willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures.
3. Be at least 18 years of age at time of informed consent.
4. Have had a diagnosis of plaque-type psoriasis (psoriasis vulgaris) for at least 12 months prior to first dose of study drug.
5. Have a PASI score of 12 or greater AND a PGA score of 3 (*moderate*) or 4 (*severe*) at Baseline/Day 1 (prior to first dose of study drug).
6. Have plaque-type psoriasis covering at least 10% of total body surface area (BSA) at Baseline/Day 1.
7. Considered by dermatologist investigator to be a candidate for systemic therapy or phototherapy of psoriasis (either naïve or history of previous treatment).
8. Considered by dermatologist investigator to have failed to respond to, or who have a contraindication to, or are intolerant to at least one conventional systemic therapy for the treatment of plaque psoriasis (including cyclosporine, methotrexate, or psoralen plus ultraviolet A light [PUVA]).

9. Sexually active women of childbearing potential are required to use adequate contraceptive methods during participation in this study. 10. No evidence of active or latent or inadequately treated infection with Mycobacterium tuberculosis (TB).
10. Are candidates for etanercept according to the approved local product labeling

Exclusion criteria

1. Currently have non-plaque forms of psoriasis, eg, erythrodermic, guttate, or pustular psoriasis, with the exception of nail psoriasis which is allowed.
2. Have evidence of skin conditions (eg, eczema) at the time of the screening or baseline visit that would interfere with evaluation of psoriasis.
3. Have current drug-induced psoriasis, eg, a new onset of psoriasis or an exacerbation of psoriasis from beta blockers, calcium channel blockers, antimalarial drugs or lithium.
4. If planned initiation of, or changes to, concomitant medication that could affect psoriasis are to occur within 2 weeks prior to randomization and/or during the study.
5. Cannot discontinue systemic therapies and/or topical therapies for the treatment of psoriasis and cannot discontinue phototherapy (UVB or PUVA).
6. Are taking or require oral or injectable (eg, intraarticular, intramuscular, or intravenous) corticosteroids for any condition.
7. Women who are pregnant or lactating, or planning pregnancy while enrolled in the study.
8. Have previously been treated with efalizumab (Raptiva).
9. Have previously been treated with etanercept (Enbrel) for any reason.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	15-03-2012
Enrollment:	56
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Enbrel
Generic name:	Etanercept
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Not applicable
Generic name:	CP-690,550
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	09-11-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-07-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-09-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-10-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	16-01-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-03-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-04-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-05-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-05-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-07-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-09-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-09-2012
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-11-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-11-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-03-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-03-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2010-020004-30-NL
ClinicalTrials.gov	NCT01241591
CCMO	NL34169.078.10