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

Published: 01-06-2006
Last updated: 14-05-2024

The objective of this study is to evaluate the dose-ranging response in safety and efficacy of R115866 0.5mg, 1mg and 2mg and R115866 placebo given once daily for the treatment of subjects with plaque psoriasis to select a dose for further clinical...

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

Summary

ID

NL-OMON30076

Source
ToetsingOnline

Brief title
Oral R115866 psoriasis dose ranging study

Condition

- Epidermal and dermal conditions

Synonym
Psoriasis

Research involving

Human

Sponsors and support

Primary sponsor: Synergie/ Ilse pharma consultancy
Source(s) of monetary or material Support: Barrier Therapeutics,Synergie;CRO of this study

Intervention

Keyword: Plaque, Psoriasis, study

Outcome measures

Primary outcome

The primary efficacy endpoint is success in the PASI, defined as a 75% or

greater reduction from baseline (Visit 2) at the end of treatment Visit 6 (week

12).

Secondary outcome

The secondary efficacy endpoint is success in the PASI50 defined as a >=50%

reduction in score relative to the baseline PASI (Visit 2).

Safety parameters:

All reported adverse events will be summarized by the number and percentage of

subjects reporting adverse events, system organ class, preferred term,

intensity, and relationship to study medication.

Laboratory parameters:

For the clinical laboratory tests including hormone levels, descriptive

statistics will be presented by treatment and visit. Additionally, shift

tables which show the number of subjects with results that are low, normal, or

high at Visit 1 versus post-Visit 1 will be tabulated by treatment and visit.• Results of the ophthalmic tests performed at Visits 1 and 6 will be presented for the percentage and number of subjects with abnormal corneal opacity, abnormal corneal surface or abnormal eye dryness.

Audiology parameters:

Audiology test results will be performed at Visits 1 and 6. The frequency and percentage of subjects in normal, mild and abnormal hearing categories will be tallied. Additionally, shift tables for Visit 6 vs. Visit 1 will be tabulated.

Psychiatric parameters:

The results of the psychiatric evaluation of depression at Visits 1, 5 and 6 will be displayed as the percentage and number of subjects with significant clinical depression (defined as a score on the CES-D >=16)

Study description

Background summary

R115866 is a second generation all-trans retinoic acid metabolism blocking agent (RAMBA). R115866 is a novel triazole derivative with cytochrome P-450 inhibiting properties with high specificity against hydroxylases involved in the metabolic inactivation pathway of all-trans retinoic acid (RA). As a result of its cytochrome P-450 inhibiting properties, treatment with R115866 leads to enhanced tissue levels of endogenous RA thereby exerting distinct retinoid-like effects (e.g., formation of a granular layer and the transformation of the parakeratotic type of keratinization to the orthokeratotic type in the scale regions of murine tail epidermis)8 in vivo.

This property and the well-known modulating effects of RA on epithelial growth and differentiation indicate R115866 is potentially useful for disorders associated with or due to an aberrant keratinization, such as psoriasis.

Study objective

The objective of this study is to evaluate the dose-ranging response in safety and efficacy of R115866 0.5mg, 1mg and 2mg and R115866 placebo given once daily for the treatment of subjects with plaque psoriasis to select a dose for further clinical development.

Study design

This is a multi-center, randomized, evaluator-blind, placebo-controlled, parallel-group study of the safety and efficacy of R115866 0.5mg, 1mg and 2mg and R115866 placebo in the treatment of severe plaque psoriasis. Subjects with plaque psoriasis on >=10% body surface area (BSA) with a Psoriasis Area and Severity Index (PASI) of >=10

Intervention

Subjects will be randomized to R115866 0.5mg, R115866 1mg, R115866 2mg or R115866 placebo. Subjects will take the assigned study medication once daily for 12 weeks. The 12-week treatment phase will be followed by an 8-week no-treatment follow up phase.

Study burden and risks

During Visit 1 patient will give informed consent, prior to any study related procedures. Also the Medical history will be discussed. Clinical evaluation will be done every visit.
Also 8-hour fasting routine clinical laboratory and select hormone sampling at visits 1, 4, 5, 6 and 8 (weeks -2, 4, 8, 12 and 20) will be taken.
Ophthalmologic and audiology evaluations: Visits 1 and 6 (weeks -2 and 12), psychiatric evaluations: Visits 1, 5 and 6 (weeks -2, 8 and 12), Electrocardiogram (ECG): Visits 1, 4, 5 and 6 (weeks -2, 4, 8 and 12) will be done.

All these procedures are standard procedures for the hospitals particpating in this study.

Contacts

Public

Synergie/ Ilse pharma consultancy

Platte Akker 38
4847KP
Nederland
Scientific
Synergie/ Ilse pharma consultancy

Platte Akker 38
4847KP
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Subject must be 18 years of older. Subject should be male or female not of childbearing potential. Subject should have a clinical diagnose of plaque psoriasis with a BSA of more then 10% and a PASI of more then 10.

Exclusion criteria

Subject has a history of sensitivity to any of the ingredients in the study medication
Subject is currently participating in, or has within the 30 days prior to the clinical trial participated in an investigational clinical trial.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2006
Enrollment:	37
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	nvy
Generic name:	Rambazole

Ethics review

Approved WMO

Date:	01-06-2006
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2005-004623-19-NL
CCMO	NL12199.091.06