A randomized, double-blind, placebo-controlled, multicenter study to demonstrate the efficacy at 16 weeks of secukinumab 150 and 300 mg s.c. and to assess safety, tolerability and long-term efficacy up to 132 weeks in subjects with moderate to severe palmoplantar psoriasis (CAIN457A2312)

Published: 10-04-2013
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Primary: To demonstrate the superiority of secukinumab 150 mg and/or 300 mg to placebo in subjects with moderate to severe palmoplantar psoriasis as assessed by the palmoplantar Investigator*s Global Assessment (ppIGA) at Week 16.Secondary: Efficacy...

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

Summary

ID

NL-OMON44761

Source
ToetsingOnline

Brief title
CAIN457A2312

Condition

- Epidermal and dermal conditions

Synonym
psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma BV

Intervention

Keyword: palmoplantar, psoriasis, secukinumab

Outcome measures

Primary outcome

ppIGA at week 16.

Secondary outcome

ppIGA, ppPASI up to week 132, adverse events.

Study description

Background summary

Plaque psoriasis (psoriasis vulgaris) is the most frequent clinical presentation of psoriasis. Palmoplantar psoriasis is a variant affecting the palms and soles, often associated with functional limitations and pain and often resistant to many forms of therapy. Palmoplantar psoriasis may have a severe impact on the quality of life.
A variety of treatments has been tried from topical treatments to UV light therapy and classic systemic treatment. None of them has been shown to be very effective. Treatment options have increased with the arrival of biological treatments, but the place of these newer treatments is not clear yet and larger prospective, controlled studies are required.
Secukinumab is a recombinant high-affinity fully human monoclonal anti-human Interleukin-17A antibody of the IgG1/*-class. Secukinumab binds to human IL-17A and neutralizes the bioactivity of this cytokine. IL-17A is pivotal in several autoimmune and inflammatory processes. Its neutralization is expected to treat the underlying pathophysiology of immune mediated disease, and as a consequence

provide relief of psoriatic symptoms.
This study aims to provide data on the use of secukinumab for moderate to severe psoriasis that includes a significant involvement of palms and soles. Phase III studies for secukinumab included assessments of psoriasis, but did not include specific assessments of palms and soles. The purpose of this study is to demonstrate the efficacy of 2 doses (150 and 300 mg) of secukinumab versus placebo at Week 16. Treatment will continue up to 132 weeks to assess long term efficacy, safety and tolerability. Patients will administer the injections themselves.
Till week 80, this study is placebo-controlled. As of week 80 (protocol version 01) there is no placebo-arm anymore and subjects of placebo-group will receive 150 mg or 300 mg secukinumab s.c. 4-weekly.

Study objective

Primary: To demonstrate the superiority of secukinumab 150 mg and/or 300 mg to placebo in subjects with moderate to severe palmoplantar psoriasis as assessed by the palmoplantar Investigator*s Global Assessment (ppIGA) at Week 16.
Secondary: Efficacy (ppIGA, ppPASI) up to week 132 Safety and tolerability. Immunogenicity.

Study design

Multicenter randomized double-blind phase III parallel-group placebo-controlled study (placebo-controlled till week 80).
Randomisation (1:1:1) to:
* Secukinumab 150 mg (s.c. injections every 4 weeks) *)
* Secukinumab 300 mg (s.c. injections every 4 weeks) *)
* Placebo.
*) after loading period of 4 week with weekly injections.
As of week 80 subjects placebo-group (group 3 above), randomisation 1:1:
* Secukinumab 150 mg (s.c. injections every 4 weeks)
* Secukinumab 300 mg (s.c. injections every 4 weeks)

Screening period of max. 4 weeks. Treatment period approx. 132 weeks. Follow-up period 8 weeks.
Evaluation of efficacy at week 16. Patients on placebo and not qualifying as ppIGA responders will be switched at week 16 to secukinumab (randomized allocation of dose).
Approx. 200 patients.

Intervention

Treatment with Secukinumab (150 or 300 mg) or placebo s.c 4-weekly.
Placebo till week 80, as of week 80 secukinumab 4-weekly 150 of 300 mg s.c. (no

placebo-arm anymore)

Study burden and risks

Risk: Adverse effects of study medication.
Burden: Study duration approx. 144 weeks. Approx. 24 visits. Fasting 6x. Duration 2 h.
Approx. 39 times s.c. administration of study medication (2 injections of 1 mL per occasion).
Physical examination during all visits.
Blood tests approx. 10 times, 5-10 ml/occasion.
ECG 7 times.
TBC skin test or blood test 1x.
Chest X ray 1x (if not performed in previous 3 months).
Optional photographs of affected areas 9 times.
4 Questionnaires (symptoms and quality of life) 4 times.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Male or female patients at least 18 years of age.
*Chronic moderate to severe plaque type psoriasis for at least 6 months with:
- significant involvement of palms and soles defined by a ppIGA score of > 3.
- at least one extra palmoplantar plaque on the skin.
* Candidate for systemic therapy, defined as having psoriasis considered inadequately controlled by:
- Topical treatment (including super potent topical corticosteroid) and/or
- Phototherapy and/or
- Previous systemic therapy.

Exclusion criteria

* Forms of psoriasis other than chronic plaque type psoriasis.
* Prior exposure to secukinumab or any other biologic drug directly targeting IL-17 or IL-17 receptor.
* Chest X-ray with evidence of ongoing infectious or malignant process.
* Pregnant or lactating women.
* Women of child-bearing potential using inadequate contraception.
* Active systemic infections during the last two weeks and/or history of chronic or recurrent infectious disease or evidence of tuberculosis infection.
* Plans for administration of live vaccines during the study period or 6 weeks prior to randomization.

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):	15-08-2013
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cosyntyx
Generic name:	secukinumab
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	10-04-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-05-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-07-2013

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-02-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-04-2015

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-08-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2012-005412-25-NL
ClinicalTrials.gov	NCT01806597
CCMO	NL43895.018.13