Long term clear skin maintenance treatment optimization in patients with moderate to severe chronic plaque psoriasis: A randomized, multicenter, open-label with blinded-assessment, comparative, 52 week study to evaluate the efficacy, safety and tolerability of secukinumab 300 mg s.c.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON42493

Source
ToetsingOnline

Brief title
CAIN457A3302 (OPTIMISE)

Condition

- Skin and subcutaneous tissue disorders NEC

Synonym
psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma B.V. (opdrachtgever / sponsor van dit onderzoek)

Intervention

Keyword: Chronic plaque psoriasis, efficacy, safety, secukinumab

Outcome measures

Primary outcome

The primary objective is to demonstrate in the patient pool of PASI 90

responders at Week 24 that secukinumab 300 mg s.c. every 6 weeks

treatment is non-inferior to secukinumab 300 mg s.c. every 4 weeks treatment

with respect to maintaining a PASI 90 response rate at

Week 52.

Secondary outcome

The key secondary objective is to demonstrate in the patient pool of PASI 75

responders who do not reach a PASI 90 response at Week 24

that secukinumab 300 mg s.c. administered every 2 weeks is superior to

secukinumab 300 mg s.c. administered every 4 weeks at Week 52 based

on the PASI 90 response rate.

Study description

Background summary

Reducing maintenance dosing regimens for patients treated with (biologic) drugs offers benefits, such as minimizing patients* exposure to the drug substance while keeping an acceptable clinical response. In contrast, patients not responding adequately to a drug substance can benefit from an increased frequency of drug dosing. In daily clinical practice, a change of the dose frequency for marketed substances can be assumed to happen often depending on the treatment response of patients. A secukinumab dose of 300 mg s.c. every 4 weeks as a maintenance treatment dose regimen has been evaluated extensively in a Phase 3 clinical trial program and shown strong sustainability of treatment response over 52 weeks

Study objective

This study will assess if a more prolonged dose interval (every 6 weeks compared to every 4 weeks) will allow psoriasis patients who achieve clear or almost clear skin after 24 weeks of secukinumab treatment - Psoriasis Area and Severity Index (PASI) * 90 - to maintain this skin response for a further 28 weeks (52 weeks in total). The study will also assess if a dose interval (dosing every 2 weeks compared to every 4 weeks) will allow psoriasis patients who fail to achieve a PASI 90 response after 24 weeks of secukinumab treatment to meet the PASI 90 response target in a further 28-week study period.

Study design

This is a randomized, open-label, assessment-blinded, multicenter, 52-week study to evaluate the efficacy (based on PASI 90), safety and tolerability of secukinumab 300 mg s.c. in patients with moderate to severe chronic plaque psoriasis. This study consists of 2 treatment periods: a 24-week run-in treatment period (Baseline to Week 24) and a 28-week maintenance treatment period (Week 24 to Week 52).
For Treatment Period 1 (Baseline to Week 24) all patients will receive the same treatment: 300 mg of secukinumab by s.c. injection with initial dosing at Weeks 0, 1, 2, and 3 followed by dosing every 4 weeks.
For Treatment Period 2 (Week 24 to Week 52) patients will be randomly assigned to one of 4 treatment groups depending on their PASI response to treatment.
Patients with PASI 90 (psoriasis clear or almost clear skin) will be randomized at Week 24 on a 1:1 basis to Group 1 or Group 2:
* Group 1 (recommended maintenance treatment): secukinumab 300 mg s.c. every 4 weeks.
* Group 2 (experimental dosing maintenance treatment): secukinumab 300 mg s.c. every 6 weeks.

Patients who do not achieve a PASI 90 response at Week 24 but achieve at least a PASI 75 response will be eligible for dose frequency intensification and will be randomized on a 1:1 basis to either Group 3 or Group 4:
* Group 3 (recommended maintenance treatment): secukinumab s.c. 300 mg every 4 weeks.
* Group 4 (experimental maintenance treatment): secukinumab s.c. 300 mg every 2 weeks.

Patients from Group 3 and Group 4 will enter a treatment-free follow-up period from Week 52 until Week 60.
Patients without a PASI 75 response at Week 24 will not be eligible for randomization and will be discontinued from the study.
Randomization will be stratified by body weight collected at the Randomization Visit (< 90 kg or * 90 kg).

Intervention

Patients with PASI 90 (psoriasis clear or almost clear skin) will be randomized at Week 24 on a 1:1 basis to Group 1 or Group 2:
* Group 1 (recommended maintenance treatment): secukinumab 300 mg s.c. every 4 weeks.
* Group 2 (experimental dosing maintenance treatment): secukinumab 300 mg s.c. every 6 weeks.

Patients who do not achieve a PASI 90 response at Week 24 but achieve at least a PASI 75 response will be eligible for dose frequency intensification and will be randomized on a 1:1 basis to either Group 3 or Group 4:
* Group 3 (recommended maintenance treatment): secukinumab s.c. 300 mg every 4 weeks.
* Group 4 (experimental maintenance treatment): secukinumab s.c. 300 mg every 2 weeks.

Study burden and risks

Burden:
More clinic visits that also take more time than routine visits.
Administration of 2 sub-cutaneous injections: 14, 16 or 22x. # is dependent on treatment group (1-4).
Physical examination, assessment severity psoriasis inclusive: Each visit; 18-19x. Inclusive assessment length 1x, weight 4-5x, bloodpressure and pulse 10-11x. # is dependent on treatment group (1-4).
ECG: 4x.
Blood collection (9-26ml per collection) + urine collection:10-11x. # is dependent on treatment group (1-4).

Female subjects: Pregancy test: 8-9x. 1x in serum and 7-8x in urine. Completion of questionnaires (7 x max 20 minuten).# is dependent on treatment group (1-4). Chest X-Ray in case this or CT- or MRI-Scan not performed within 3 months before screening and assessment is available.

Risks:
Possible risks are adverse events of secukinumab and burden/risks of study procedures.

Contacts

Public
Novartis

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NL
Scientific
Novartis

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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. Men or women * 18.
2. Chronic plaque-type psoriasis diagnosed for at least 6 months prior to Screening and

candidate for systemic therapy.
3. Moderate to severe psoriasis at Baseline as evidenced by:
* PASI * 10 and
* IGA mod 2011 score of 3 or higher (based on a scale of 0 to 4) and
* BSA affected by plaque-type psoriasis of * 10%.

Exclusion criteria

1. History of exposure to any biologic drug taken for the treatment of chronic plaque psoriasis or any other indication including but not limited to anti-tumor necrosis factor (TNF) alpha, anti-interleukin (IL)12/23, or any anti-IL-17A or IL-17A receptor (IL 17AR) antibody.
2. History of hypersensitivity to any of the study drugs or to drugs of similar chemical classes including latex hypersensitivity.
3. Forms of psoriasis other than chronic plaque-type (eg, pustular, erythrodermic and guttate psoriasis).
4. Drug-induced psoriasis (ie, new onset or current exacerbation from beta-blockers, calcium channel inhibitors or lithium).
5. Ongoing use of prohibited psoriasis treatments (eg, topical or systemic corticosteroids, ultraviolet (UV) therapy).
6. Ongoing use of other non-psoriasis prohibited treatments. Washout periods detailed in the protocol have to be adhered to. All other prior non-psoriasis concomitant treatments must be at a stable dose as detailed in the protocol before initiation of study drug.
7. Pregnant or nursing (lactating) women, where pregnancy is defined as the state of a female after conception and until the termination of gestation, confirmed by a positive human chorionic gonadotropin (hCG) laboratory test (> 5 mIU/mL).
8. Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using effective methods of contraception during entire study or longer if
required by locally approved prescribing information (e.g. in EU 20 weeks).
9. Active ongoing inflammatory diseases other than psoriasis that might confound the evaluation of the benefit of secukinumab therapy.
10. Underlying condition (including, but not limited to metabolic, hematologic, renal, hepatic, pulmonary, neurologic, endocrine, cardiac, infectious or gastrointestinal conditions) which, in the opinion of the Investigator, significantly immunocompromises the patient and/or places the patient at unacceptable risk for receiving an immunomodulatory therapy.;See protocol for other exclusion criteria.

Study design

Design

Study phase: 3

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-08-2015
Enrollment:	40
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	19-03-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	16-06-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	06-07-2015
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-07-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-08-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-08-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-10-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-10-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-10-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	EUCTR2014-005339-15-NL
ClinicalTrials.gov	NCT02409667
CCMO	NL52659.060.15