A randomized, double-blind, multicenter study assessing short (16 weeks) and long-term efficacy (up to 1 year), safety, and tolerability of 2 subcutaneous secukinumab dose regimens in adult patients with moderate to severe hidradenitis suppurativa (SUNRISE)

Published: 15-01-2019
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Main Objective:To demonstrate the efficacy of secukinumab compared to placebo withrespect to HiSCR after 16 weeks of treatment.Secondary objective:To demonstrate the efficacy of secukinumab compared to placebo after 16 weeks of treatment with...

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

Summary

ID

NL-OMON52934

Source
ToetsingOnline

Brief title
CAIN457M2302 (SUNRISE)

Condition

- Skin and subcutaneous tissue disorders NEC

Synonym
Hidradenitis suppurativa; Purulent hairfollicle inflamation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Efficacy, Hidradenitis Suppurativa, Safety

Outcome measures

Primary outcome

Achievement of HiSCR at Week 16. HiSCR is defined as at least a 50% decrease in Abscess and Inflammatory Nodule (AN) count with no increase in the number of abscesses or in the number of draining fistulae.

Secondary outcome

* Percentage change from baseline in AN count at Week 16

* Flaring up to Week 16. Flare is defined as at least a 25% increase in AN counts with a minimum increase of 2 AN relative to baseline.

* Achievement of NRS30 at Week 16, among subjects with baseline NRS >= 3. NRS30 is defined as at least a 30% reduction and at least 2 unit reduction from baseline in Patient's Global Assessment of Skin Pain - at worst

Study description

Background summary

The purpose of this study is to demonstrate superiority of secukinumab at Week 16, based on HiSCR rates versus placebo, along with the maintenance of efficacy of secukinumab at Week 52 in subjects with moderate to severe HS. Moreover, this study will also assess the safety and tolerability of secukinumab. See paragraph 1.1 of the protocol for full details on the background of the study.

Study objective

Main Objective:
To demonstrate the efficacy of secukinumab compared to placebo with respect to HiSCR after 16 weeks of treatment.

Secondary objective:
To demonstrate the efficacy of secukinumab compared to placebo after 16 weeks of treatment with respect to AN count.
To demonstrate the efficacy of secukinumab compared to placebo after 16 weeks of treatment with respect to:
* proportion of patients with HS flares
* proportion of patients with clinical response in HS related skin pain.

Study design

This is a multicenter, randomized, double-blind, placebo controlled, parallel group study with two secukinumab dose regimens in approximately 541 patients with moderate to severe HS. The study consists of: Screening (up to 4 weeks), Treatment Period 1 (16 weeks) and Treatment Period 2 (36 weeks). Subjects who prematurely discontinue the study, or who complete the study and cannot or do not wish to continue in a planned optional extension study, will enter a post-treatment Follow-Up period (8 weeks).

Intervention

* Secukinumab 300 mg solution for s.c. injection in a 2 ml PFS
* Placebo solution for s.c. injection in a 2 ml PFS

Study burden and risks

Participants have a chance of possible side effects:
• Among the very common side effects (in more than 1 in 10 subjects) are upper respiratory tract infections with symptoms such as a stuffy nose, runny nose, itchy nose, sore throat (inflamed nose and / or throat) and a stuffy nose with

pain in the face (sinus inflammation).
• Common side effects (affects 1 in 10 to 100 subjects) include diarrhea and itchy skin rash.
• Unusual side effects (affects 1 in 100 to 1,000 subjects) include a fungal infection of the mouth and a low white blood cell count.
• Secukinumab can reduce the body's defense against infections. As a result, you may be more susceptible to infections and possibly have an increased chance of developing cancer. The infections reported during investigations were usually not serious. Up to now no problems regarding cancer have been reported.
• In patients with Crohn's disease, a (severe) worsening of this bowel disease was observed in some cases during treatment with secukinumab, but also with placebo.
• There have also been subjects who received a new inflammation of the intestine during a study with secukinumab.
• During treatment with secukinumab in daily practice, fungal infections (with candida) of the mucous membranes and skin have been reported. In most cases, this infection was not serious and the doctor did not have to interrupt the treatment.
• Also report to the researcher if you are allergic to latex.
• A hypersensitivity reaction to the study medication can occur, immediately after or many days after an injection. A severe hypersensitivity reaction can be life-threatening. Symptoms of an allergic reaction include skin rash, itching, difficulty or wheezing, lowering of blood pressure, swelling of the throat, eyes or around the mouth, rapid heartbeat, fever, sweating or shivering. Contact the researcher directly or call for other medical assistance immediately if this affects you.
• It is unknown whether secukinumab has harmful effects for women who are pregnant and babies. No problems have been reported in this area so far.
• You must not be vaccinated with live vaccines during treatment with secukinumab.
• Secukinumab is still under investigation. This means that side effects can occur that are still unknown.

The following test tests may entail the risks mentioned.
- Blood sampling: blood samples can hurt or cause a bruise. Sometimes somebody faints. Rarely, a blood clot or an infection develops on the puncture site

Contacts

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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. Written informed consent must be obtained before any assessment is performed.
2. Male and female patients >= 18 years of age.
3. Diagnosis of HS >= 1 year prior to baseline.
4. Patients with moderate to severe HS defined as:
* A total of at least 5 inflammatory lesions, i.e. abscesses and/or inflammatory nodules
AND
* Inflammatory lesions should affect at least 2 distinct anatomic areas
5. Patients agree to daily use of topical over-the-counter antiseptics on the areas affected by HS lesions while on study treatment.

Exclusion criteria

1. Total fistulae count >= 20 at baseline.
2. Any other active skin disease or condition that may interfere with assessment of HS.
3. Active ongoing inflammatory diseases other than HS that require treatment with prohibited medications (see Table 6 2).
4. Use or planned use of prohibited treatment. Washout periods detailed in the

protocol have to be adhered to (see Table 6 2).
5. History of hypersensitivity to any of the study drug constituents.
6. History of lymphoproliferative disease or any known malignancy or history of malignancy of any organ system treated or untreated within the past 5 years, regardless of whether there is evidence of local recurrence or metastases (except for skin Bowen*s disease, or basal cell carcinoma or actinic keratoses that have been treated with no evidence of recurrence in the past 12 weeks; carcinoma in situ of the cervix or non-invasive malignant colon polyps that have been removed).
7. Pregnant or lactating women.

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):	19-12-2019
Enrollment:	6
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	15-01-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-03-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-06-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-09-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-12-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	31-12-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	31-07-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	12-08-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-03-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-09-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-10-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-03-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-04-2022
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	EUCTR2018-002062-39-NL
ClinicalTrials.gov	NCT03713632
CCMO	NL67727.100.18