



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)

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Main Information

Primary registry identifying number

LBCTR2019020191

Protocol number

CAIN457M2302

MOH registration number

Study registered at the country of origin

Yes

Study registered at the country of origin: Specify

Type of registration

Prospective

Type of registration: Justify

N/A

Date of registration in national regulatory agency

Primary sponsor

Novartis Pharma Services Inc.

Primary sponsor: Country of origin

Novartis Pharmaceuticals

Date of registration in primary registry

14/10/2020

Date of registration in national regulatory agency

Public title

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)

Acronym

SUNRISE

Scientific title

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)

Acronym

Brief summary of the study: English

The purpose of this study is to demonstrate superiority of secukinumab at Week 16, based on Hidradenitis Suppurativa Clinical Response (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.

Brief summary of the study: Arabic

دراسة متعددة المراكز ومزدوجة التعمية وعشوائية التوزيع لتقييم الفعالي (أسبوعاً) والطويلة الأمد (لغاية سنة واحدة) لنظامي جرعات تحت الجلد من دواء سيكوكينوماب لدى 16 والسلامة وقدرة التحمل القصيرة الأمد (SUNRISE سانرايز) مرضى بالغين مصابين بالتهاب الغدد العرقية القحبي

Health conditions/problem studied: Specify





Patients with Hidradenitis Suppurativa

Interventions: Specify

Drug: Secukinumab
Drug: Placebo

Key inclusion and exclusion criteria: Inclusion criteria

- Written informed consent must be obtained before any assessment is performed.
- Male and female patients ≥ 18 years of age.
- Diagnosis of HS ≥ 1 year prior to baseline.
- 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
- Patients agree to daily use of topical over-the-counter antiseptics on the areas affected by HS lesions while on study treatment.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

99

Key inclusion and exclusion criteria: Exclusion criteria

- Total fistulae count ≥ 20 at baseline.
- Any other active skin disease or condition that may interfere with assessment of HS.
- Active ongoing inflammatory diseases other than HS that require treatment with prohibited medications.
- Use or planned use of prohibited treatment. Washout periods detailed in the protocol have to be adhered to.
- History of hypersensitivity to any of the study drug constituents.
- 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).
- Pregnant or lactating women.

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Other

Trial scope: Specify scope

Study design: Allocation

Randomized controlled trial

Study design: Masking

Blinded (masking used)

Study design: Control

Placebo

Study phase

3

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Parallel

Study design: Specify assignment

N/A

IMP has market authorization

Yes, Lebanon and Worldwide

IMP has market authorization: Specify

Worldwide

Name of IMP

Secukinumab (Cosentyx)

Year of authorization

2016

Month of authorization

3

Type of IMP



Immunological

Pharmaceutical class

Secukinumab is selective for human IL-17A and potently neutralizes the bioactivity of this cytokine. IL-17A is the central cytokine in multiple autoimmune and inflammatory processes. It is being recognized as one of the principal pro-inflammatory cytokines in autoimmune diseases such as psoriasis, PsA and AS and is thought to play a role in other inflammatory conditions.

Therapeutic indication

Patients with:

- Psoriasis (Pso)
- Ankylosing Spondylitis (AS)
- Psoriatic Arthritis (PsA)

Therapeutic benefit

Secukinumab has demonstrated positive benefit-risk in the treatment of multiple chronic inflammatory indications including moderate to severe plaque psoriasis, ankylosing spondylitis, psoriatic arthritis.

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

Samples with DNA**

Biospecimen description

Samples will be sent to Q Squared Solutions central Lab in UK as per study protocol to assess patient disease response following treatment administration.

Target sample size

8

Actual enrollment target size

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

15/04/2019

Date of study closure: Type

Anticipated

Date of study closure: Date

29/07/2022

Recruitment status

Recruiting

Recruitment status: Specify

**Date of completion**

16/02/2021

IPD sharing statement plan

No

IPD sharing statement description

Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.

This trial data availability is according to the criteria and process described on www.clinicalstudydatarequest.com

Additional data URL

<https://www.clinicaltrials.gov/ct2/show/NCT03713632?term=AIN457&recrs=ab&cond=Hidradenitis+Suppurativa&rank=1>

Admin comments**Trial status**

Approved

Secondary Identifying Numbers

| Full name of issuing authority | Secondary identifying number |
|---|------------------------------|
| National Institute of Health (clinicaltrials.gov) | NCT03713632 |

Sources of Monetary or Material Support

| Name |
|-------------------------------|
| Novartis Pharma Services Inc. |

Secondary Sponsors

| Name |
|------|
| NA |

Contact for Public/Scientific Queries

| Contact type | Contact full name | Address | Country | Telephone | Email | Affiliation |
|--------------|-------------------|------------|---------|------------------------|-------------------------------|------------------------------|
| Public | Hadi Hamam | Saida | Lebanon | 9613795246 | hadihamam@hotmail.com | Hammou Hospital |
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| Public | Roy Moutran | Beirut | Lebanon | 9613592192 | roymoutran@yahoo.com | Mount Lebanon Hospital |



Centers/Hospitals Involved in the Study

| Center/Hospital name | Name of principles investigator | Principles investigator speciality | Ethical approval |
|--|---------------------------------|------------------------------------|------------------|
| Hammoud Hospital University Medical Center | Dr Hadi Hamam | Dermatology | Approved |
| Mount Lebanon Hospital | Dr Roy Moutran | Dermatology | Approved |

Ethics Review

| Ethics approval obtained | Approval date | Contact name | Contact email | Contact phone |
|--|---------------|---------------|----------------------------|-----------------------------|
| Hammoud Hospital University Medical Center | 20/12/2018 | Ahmad Zaatari | aatari@hammoudhospital.com | +961 (0) 7 723111 ext 1160 |
| Mount Lebanon Hospital | 30/04/2019 | Marie Merheb | Marie.merheb@mlh.com.lb | +961 (0) 5 957 000 exr 1200 |



Countries of Recruitment

| Name |
|--------------------------|
| Belgium |
| Argentina |
| Bulgaria |
| Croatia |
| Czech Republic |
| Brazil |
| Canada |
| Colombia |
| France |
| Denmark |
| Germany |
| Guatemala |
| India |
| Greece |
| Hungary |
| Lebanon |
| Malaysia |
| Italy |
| Turkey |
| United Kingdom |
| United States of America |

Health Conditions or Problems Studied

| Condition | Code | Keyword |
|--------------------------|----------------------------------|--------------------------|
| Hidradenitis Suppurativa | Hidradenitis suppurativa (L73.2) | Hidradenitis Suppurativa |



Interventions

| Intervention | Description | Keyword |
|---|---|---|
| Reference table 8-1 of the study protocol: Obtain informed consent (ICF), Demography, Inclusion / Exclusion criteria, Washout evaluation / instruction, Relevant medical history / current medical condition, HS medical history and previous therapies, Smoking history, Hurley stage, Prior / concomitant medications, Adverse Events, Physical Examination, Body Height, Body Weight, Vital Signs, Tuberculosis test, Lesion count (physician), Numerical Rating, Scale for pain assessment, Modified Hidradenitis Suppurativa Score (mHSS), HS-Physician's Global Assessment, Patient's Lesion Count, DLQI, EQ5D, Patient Global Impression of severity (PGI-s), Patient Global Impression of change (PGI-c), Work productivity Activity Impairment (WPAI) | ICF, Lab, questionnaires, Medication administration, physical examination | ICF, Lab tests, Questionnaires, Medication administration |

Primary Outcomes

| Name | Time Points | Measure |
|--|-------------|----------|
| Proportion of patients with Hidradenitis Suppurativa Clinical Response (HiSCR) | 16 weeks | 16 weeks |

Key Secondary Outcomes

| Name | Time Points | Measure |
|---------------------------------------|-------------|----------|
| Participants achieving NRS30 | 16 weeks | 16 weeks |
| Proportion of patients with HS flares | 16 weeks | 16 weeks |



Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files