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
01/04/2019

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 وعشوائيّة التوزيع لتقييم الفعالي
أسبوعًا) والطويلة الأمد (لغاية سنة واحدة) لنظاميّ جرعات تحت الجلد من دواء سيكوكينوماب لدى16والسلامة وقدرة التحمّل القصيرة الأمد (
سانرايز) مرضى بالغين مصابين بالتهاب الغدد العرقيّة القيحيّ SUNRISE)

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

Pending

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
Scientific	Hind Khairallah	Sin El Fil	Lebanon	+961 1 512002 Ext. 271	Hind.Khairallah@fattal.com.lb	Khalil Fattal et Fils s.a.l.

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

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

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