A Phase 2, Multicenter, Randomized, Placebo-Controlled, Double-Blind Study to Evaluate the Safety and Efficacy of Risankizumab in Adult Subjects with Moderate to Severe Hidradenitis Supperativa.

Published: 22-07-2019
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Ethical review	Approved WMO
Status	Completed
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON50087

Source
ToetsingOnline

Brief title
M16-833

Condition

- Autoimmune disorders
- Skin and subcutaneous tissue disorders NEC

Synonym
Acne Inversa, Infected Sweat Glands

Research involving
Human

Sponsors and support

Primary sponsor: AbbVie B.V.
Source(s) of monetary or material Support: AbbVie

Intervention

Keyword: hidradenitis suppurativa, Risankizumab

Outcome measures

Primary outcome

The primary endpoint is the proportion of subjects achieving Hidradenitis Suppurativa Clinical Response (HiSCR) at Week 16. HiSCR is defined as at least a 50% reduction in the total inflammatory nodule [AN] count with no increase in abscess count and no increase in draining fistula count relative to baseline.

Secondary outcome

Proportion of subjects achieving at least 30% reduction and at least 1 unit reduction from Baseline in NRS30 in PGA Skin Pain at Week 8 among subjects with Baseline Numerical Rating Scale (NRS) >= 3.

Proportion of subjects achieving NRS30 in PGA Skin Pain at Week 16 among subjects with Baseline NRS >= 3.

Proportion of subjects who experience at least 25% increase in AN counts with a minimum increase of 2 relative to Baseline during Period A.

Change from Baseline in DLQI at Week 16.

Change from Baseline in HS-related swelling - assessed based on the HSSA at Week 16.

Change from Baseline in HS-related odor - assessed based on the HSSA

at Week 16.

Change from Baseline in HS-related worst drainage - assessed based on

the HSSA at Week 16.

Study description

Background summary

Hidradenitis suppurativa (HS) is an inflammatory, debilitating skin disease with a characteristic clinical presentation of recurrent or chronic painful or suppurating lesions that most commonly present in
the axilla, inguinal, and anogenital regions.
This study will provide essential data for risankizumab registration as treatment for patients
with moderate to severe HS, as there is still a high unmet need for new safe and efficacious HS therapies.
The primary hypothesis for the study is that risankizumab will provide superior efficacy compared to placebo and will be well tolerated in subjects with Hidradentitis Supperativa.

Study objective

The objective of this study is to assess the safety and efficacy of 2 dose levels of risankizumab versus placebo for the treatment of signs and symptoms of moderate to severe Hidradentitis Supperativa in adult subjects diagnosed for at least one year before the Baseline visit.

Study design

This is a phase-2 multi-center, randomized, double-blinded, parallel-group, placebo-controlled study to evaluate the safety and efficacy of 2 dose levels of risankizumab in adult subjects with moderate to severe HS diagnosed at least 1 year before Baseline Visit. The study compromises a 35*day screening period, and a 68-week study period. The follow*up period consists of a follow*up phone call 20 weeks after the last study drug dose.
The study is designed to enroll 220 subjects worldwide.

Intervention

This study includes two treatment periods. Eligible Subjects will be randomized to receive risankizumab or placebo in a 1:1:1 ratio:

Period A (16 weeks):
Subjects will receive risankizuamb or placebo until Week 12 visit:
• Risankizumab subcutaneous (SC) injection (dose A) ; OR
• Risankizumab subcutaneous (SC) injection (dose B) ; OR
• Placebo subcutaneous (SC) injection
Period B (52 weeks):
At Weeks 16, 17, 18, subjects initially randomized to the placebo arm will receive blinded risankizumab. Patients who were initially randomized to the risankizumab arm will receive blinded matching placebo. Starting from week 20 all subjects will receive open-label risankizumab.
Risankizumab and placebo will be administrated subcutaneously with pre-filled syringes.

Study burden and risks

There is a higher burden for subjects participating in this study compared to receiving standard medical care. Subjects will be visiting the hospital more frequently. During these visits study procedures will be performed including blood sampling and questionnaires. Subjects will also be tested for tuberculosis (TB), hepatitis B (HBV), hepatitis C (HCV), and human immunodeficiency virus (HIV). Women of childbearing potential are required to practice a method of birth control both during the study and through 20 weeks after the last dose of study drug and are tested for pregnancy during the study. The most common side effects reported during previous studies of risankizumab were upper respiratory infections, feeling tired, fungal skin infection, injection site reactions and headache.

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

• Subjects must be >= 18 years old at Screening with a clinical diagnosis of moderate to severe HS (defined as a total AN count of >= 5 at Baseline, presence of HS lesions in at least 2 distinct anatomic areas, and draining fistula count of <= 20 at Baseline) for at least 1 year prior to Baseline, as determined by the investigator (i.e., through medical history, interview of subject).
• Subjects must have a history of inadequate response or intolerance to an adequate trial of oral antibiotics for treatment of HS.
• Prior exposure to anti-IL12/23/17 (overall, no more than 10% of the study population)
• Prior exposure to anti-TNF (overall, no more than 15% of the study population)

Exclusion criteria

No history of active skin disease other than HS that could interfere with the assessment of HS.
No active TB or concurrent treatment for latent TB and no evidence of HBV, HCV or HIV.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-01-2020
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Risankizumab
Generic name:	Risankizumab

Ethics review

Approved WMO Date:	22-07-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-10-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-11-2019

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-11-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-12-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-03-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-05-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-07-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-07-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-09-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	03-03-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-07-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-09-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2019-000122-21-NL
ClinicalTrials.gov	NCT03926169
CCMO	NL69816.078.19

Study results

Date completed:	02-08-2021

Results posted: 17-08-2022

Summary results
Trial ended prematurely

First publication
03-06-2022

URL result
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

Internal documents
File