An open-label, long-term extension trial of spesolimab treatment in adult patients with Hidradenitis Suppurativa (HS)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin appendage conditions
Study type	Interventional

Summary

ID

NL-OMON56233

Source
ToetsingOnline

Brief title
OLE study: spesolimab in HS, extension of 1368-0052 trial.

Condition

- Skin appendage conditions

Synonym
a skin disease called hidradenitis suppurativa, Verneuil's disease

Research involving
Human

Sponsors and support

Primary sponsor: IQVIA RDS Netherlands B.V.
Source(s) of monetary or material Support: Boehringer Ingelheim

Intervention

Keyword: Dermatology, Hidradenitis suppurativa, Skin disease, Spesolimab

Outcome measures

Primary outcome

The primary endpoint is the occurrence of treatment emergent adverse events (TEAEs) up to the end of the maintenance treatment period including REP (i.e., 16 weeks after the last study treatment).

Secondary outcome

• Percentage change in total abscess and inflammatory nodule (AN) count from baseline up to Week 12.

• Percentage change in total draining fistula (DF) count from baseline up to Week 12.

• Hidradenitis Suppurativa Clinical Response (HiSCR) up to Week 12.

• Change from baseline in International Hidradenitis Suppurativa Severity Score System (IHS4) value up to Week 12.

• Hidradenitis Suppurativa Physician Global Assessment (HS-PGA) score of 0 or 1 up to Week 12.

• Absolute change from baseline in Hidradenitis Suppurativa Area and Severity Index (HASI) score up to Week 12.

• Number of patients having at least one flare (defined as at least 25 % increase in AN count with a minimum increase of 2 relative to baseline) up to Week 12.

• Number of patients having at least 30% reduction from baseline in Numerical

Rating Scale (NRS30) in Patient*s Global Assessment of HS Pain up to Week 12.

Study description

Background summary

Hidradenitis suppurativa (HS) is an inflammatory skin disease characterised by recurrent, painful abscesses and fistulous tracts. Patients with HS objectively have one of the lowest quality of life measures of any dermatologic disease. Lesions characteristically occur in the axillary, groin, infra mammary, and/or anogenital regions of the body. HS lesions may progress to form sinus tracts and expansive abscesses. Sequelae include significant pain, scarring, and psychological distress. The average age of onset is during the early 20s. The global prevalence of HS is reported between 0.0003% and 4.1%. Underdiagnosis or improper diagnosis is common. Overall, HS prevalence varies significantly based on study
methodology; however, the disease appears to be more common than was previously considered.
Treatment often begins with topical or oral antibiotics. When topical medications and oral antibiotics fail, or the disease has progressed, biologics are recommended. Adalimumab is the only approved biologic, with the response rate of 42%-59% versus placebo response of 26% - 28%, with a schedule of weekly subcutaneous (s.c.) dosing.
When the medical management is ineffective, surgery is the option. Some of the most burdensome HS symptoms from patient perspective are pain, drainage and explosive openings, itch, skin tightness (scarring), odour, fatigue and flu-like symptoms. Patients reported to be unsatisfied with the level of control offered by currently available treatment options and unmet needs from the patient perspective include the need for new medical treatments with favourable efficacy and tolerability profiles. In qualitative evidence, the most important treatment goals from the patient perspective were pain, drainage (including explosive openings) and fatigue.

Study objective

The primary objective of this trial is to assess the long-term safety of spesolimab in patients with HS who have completed the 1368-0052 PoCC trial and are qualified for entry into this trial. The secondary objectives are to evaluate efficacy at a lower dose than tested in PoCC trial.

Study design

Open label, single-arm, multi-regimen, 2-year extension study in adult patients with HS who have completed their treatment in the 1368-0052

PoCC trial, with a total treatment duration of 2 years.
Approximately 45 patients will be randomized.

Intervention

Spesolimab (BI 655130) or matching placebo at visit 1. Thereafter, patients are only treated with spesolimab.

Patients from the placebo arm of the 1368-0052 trial will be given an initial 1200 mg i.v. loading dose of spesolimab, followed by 600 mg spesolimab s.c. every two weeks. Patients from the active arm of the 1368-0052 trial will be given a loading dose of placebo followed by 600 mg spesolimab s.c. every two weeks.

Total duration of intervention: 104 weeks.

Study burden and risks

Burden/ possible risk:
- Patient may experience side effects or adverse events of the study drug
- Patient may experience discomfort due to the procedures and measurements during the study
- Additional procedures and measurements will be performed (outside SoC), as described in the protocol (v1.0 / 16 Dec 2020)
- Participating in the study will take extra time
- Patient will be asked to fill out questionnaires and complete diaries
- Patient needs to adhere to the study schedule

Possible benefit:
- Spesolimab may improve the symptoms associated with HS
- Participation in the study helps researchers gain a better understanding of HS.

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

- Patients who have completed treatment in the parent HS spesolimab trial (1368-0052) without premature discontinuation.

Exclusion criteria

- Women who are pregnant, nursing, or who plan to become pregnant while in the trial.
- Patients who experienced study treatment-limiting adverse events during the 1368-0052 parent trial.
- Severe, progressive, or uncontrolled condition such as renal, hepatic, haematological, endocrine, pulmonary, cardiac, neurologic, cerebral, or psychiatric disease, or signs and symptoms thereof.
- Any condition which in the opinion of the investigator affects the safety of the patient, the patient's ability to participate in this trial or could compromise the quality of data.
- Any suicidal behaviour in the past 2 years (i.e. actual attempt, interrupted attempt, aborted attempt, or preparatory acts or behaviour).
- Any suicidal ideation of type 4 or 5 on the C-SSRS in the past 3 months (i.e. active suicidal thoughts with method and intent but without specific plan, or active suicidal thoughts with method, intent and plan).

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-07-2021
Enrollment:	3
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	NA
Generic name:	Spesolimab

Ethics review

Approved WMO Date:	20-05-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-08-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	03-08-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-08-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-11-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-11-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-10-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-11-2023
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	EUCTR2020-005587-55-NL
CCMO	NL77096.100.21