# Randomized, double-blind, placebo-controlled, study of spesolimab in patients with moderate or severe hidradenitis suppurativa.

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The primary objective is to estimate the effect of spesolimab compared to placebo for the mean percent change from baseline in total abscessand inflammatory nodule count at Week 12. Secondary objectives are the evaluation of efficacy of spesolimab…

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

## Summary

### ID

NL-OMON51225

**Source**
ToetsingOnline

**Brief title**
A study to test whether spesolimab helps people with HS.

### Condition

- Skin appendage conditions

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

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Boehringer Ingelheim

**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 percent change from baseline in total abcess and inflammatory nodule count at Week 12.

### Secondary outcome

Secondary endpoints are defined as described below:

- Percent change from baseline in draining fistula count at Week 12

- Percentage of patients achieving Hidradenitis Suppurativa Clinical Response (HiSCR) at Week 12. HiSCR is defined as at least a 50% reduction in the total AN count with no increase in abscess count and no increase in draining fistula count relative to baseline.

- Absolute change from baseline in International Hidradenitis Suppurativa Severity Score System (IHS4) value at Week 12

- Absolute change from baseline in HASI score at Week 12

- Percentage of patients achieving PGA score of 0 or 1 at Week 12

- Percentage of patients with at least 30% reduction from baseline in Numerical rating scale (NRS30) in Patient*s Global Assessment of HS Pain at Week 12

- Complete elimination of draining fistulas at Week 12

- 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.

- Absolute change from baseline in DLQI Score at Week 12.

- Absolute change from baseline in HiS-QoL Total Score at 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, such as topical clindamycin and oral tetracycline, followed by the use of rifampicin if there is no improvement. 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 dosing. When the medical management is ineffective, surgery is the only 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.

### Study objective

The primary objective is to estimate the effect of spesolimab compared to placebo for the mean percent change from baseline in total abscess and inflammatory nodule count at Week 12. Secondary objectives are the evaluation of efficacy of spesolimab on secondary endpoints versus placebo.

### Study design

This is an international, phase IIa multi-center, double-blind, placebo

controlled trial assessing the efficacy and safety of spesolimab in patients with moderate to severe HS, with a total treatment duration of 12 weeks. Approximately 45 patients will be randomized, of which 30 will receive spesolimab, and 15 will receive placebo.
At the end of the study all patients can participate in an open-label extension study. If patients do no want to participate, the follow-up period will be 16 weeks.

If patients agree to roll-over to the open-label extension study, they do not have to complete the follow-up period.
They will be assessed for safety and efficacy every 2 weeks by a study doctor. This will go on for 12 weeks. The next 6 months patients will be assessed every 4 weeks, and after this every 12 weeks.
Safety lab tests will be done every 4 weeks for all patients.

If patients continue in the open-label extension study (1368-0067), they do not need to complete the follow-up period (1368-0052).
The follow-up period for patients enrolled in the 1368-0067 study is as follows:
Patients are assessed by the investigator for the safety and efficacy on a weekly basis for 12 weeks.
Thereafter, patients are assessed every 4 weeks for the next six months, then every 12 weeks thereafter.
Lab safety tests are performed every 4 weeks for all patients.

**Intervention**

Spesolimab (BI 655130) or matching placebo
1x per week 1200 mg i.v. in week 0, 1 en 2
1x per two weeks 1200 mg s.c. in week 4, 6, 8 en 10
Total duration of intervention: 12 weeks.

2/3 of total number of patients receives spesolimab
1/3 of total number of patients receives placebo.

**Study burden and risks**

Burden/ possible risk:
- Worsening of HS if patient is in placebo group
- 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 / 29 Oct 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

**Public**
Boehringer Ingelheim

Comeniusstraat 6
Alkmaar 1817MS
NL
**Scientific**
Boehringer Ingelheim

Comeniusstraat 6
Alkmaar 1817MS
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

1. Male or female adult patients, 18 years of age or older.
2. Signed and dated written informed consent in accordance with ICH Good Clinical Practice (GCP) and local legislation prior to the start of any screening procedures.
3. Moderate to severe HS, based on IHS4 criteria, for at least 1 year prior to the baseline visit, as determined by the investigator through participant

interview and/or review of the medical history.
4. HS lesions in at least 2 distinct anatomic area (right/left axillary, inguinal,inframammary, perineal)
5. Biologic naive or TNFi-failure for HS.
6. Inadequate response to an adequate course of appropriate oral antibiotics for treatment of HS in the last 1 year, as per investigator discretion. This is not applicable for TNFi-failure patients
7. Total abscess and inflammatory nodule (AN) count of greater than or equal to 5.
8. Total draining fistula count of less than or equal to 20.
9. Women of childbearing potential (WOCBP1) must be ready and able to use highly effective methods of birth control per ICH M3 (R2) that result in a low failure rate of less than 1% per year when used consistently and correctly, for the duration of the trial and 16 weeks after last administration. A list of contraception methods meeting these criteria is provided in the patient information.

## Exclusion criteria

1. Presence of active skin lesions other than HS that interferes with the assessment of HS.
2. Use of restricted medications as below. Please see section 4.2.2 for further information.
- Topical corticosteroids within 1 week of Visit 2
- Systemic antibiotics within 4 weeks of visit 2.
- Systemic non-biologic therapies for HS within 4 weeks of visit 2.
- Biologic use within 12 weeks or 5 half-lives, whichever is longer, prior to visit 2.
- Opioid analgesics within 2 weeks of visit 2.
- Live virus vaccine within 6 weeks of visit 2.
3. Prior exposure to IL-36R inhibitors including spesolimab.
4. Patients who must or choose to continue the intake of restricted medications (see section 4.2.2.1) or any drug considered likely to interfere with the safe conduct of the trial.
5. Treatment with any investigational device or investigational drug of chemical or biologic nature within a minimum of 30 days or 5 half-lives of the drug, whichever is longer, prior to visit 2.
6. Women who are pregnant, nursing, or who plan to become pregnant while in the trial.
Women who stop nursing before the study drug administration do not need to be excluded from participating.
7. History of allergy/hypersensitivity to the systemically administered trial medication agent or its excipients.
8. Patient with a transplanted organ (with exception of a corneal transplant > 12 weeks prior to screening) or who have ever received stem cell therapy (e.g.,

Remestemcel-L).
9. Any documented active or suspected malignancy or history of malignancy within 5 years prior to the screening visit, except appropriately treated basal cell carcinoma of the skin, squamous cell carcinoma of the skin or in situ carcinoma of uterine cervix.
10. Active or latent TB:
o Patients with active tuberculosis should be excluded.
o Patients will be screened with Interferon Gamma Release Assay (IGRA) such as QuantiFERON or T-spot. Patients with positive IGRA are excluded unless they have completed treatment for active or latent tuberculosis per investigator discretion, at the time of screening.
o Patients with indeterminate QuantiFERON or invalid/borderline T-spot may be retested with IGRA (once) and if inconclusive should have a PPD skin test.
o PPD skin test, also called Tuberculin- Skin testing (TST), can be performed if IGRA is not available or inconclusive. A tuberculin skin test reaction *10mm (*5mm if receiving *15mg/d prednisone or other immunosuppressant) is considered positive. Patients with a positive TST are excluded unless they have completed treatment as above.
11. Active systemic infection within 2 weeks of visit 2. Patients can be re-screened after treatment of the acute infection, as per investigator discretion.
12. Relevant chronic infections as determined by the investigator, including human immunodeficiency virus (HIV) or viral hepatitis. In case of a positive hepatitis C antibody test, a positive reflex testing for Hepatitis C RNA PCR is considered positive.
13. Major surgery (major according to the investigator) performed within 12 weeks prior to first study drug administration or planned during the study (e.g. hip replacement, aneurysm removal, stomach ligation)
14. Severe, progressive, or uncontrolled hepatic disease, defined as >3-fold Upper Limit of Normal (ULN) elevation in AST or ALT or alkaline phosphatase, and >2-fold ULN elevation in total bilirubin.
15. Evidence of a current or previous disease, medical condition (including chronic alcohol or drug abuse or any condition) other than HS, surgical procedure, psychiatric or social problems, medical examination finding (including vital signs and ECG), or laboratory value at the screening outside the reference range that in the opinion of the investigator is clinically significant and would compromise the safety of the patient or compromise the quality of the data, make the study participant unreliable to adhere to the protocol, comply with all study visits/procedures or to complete the trial.
16. Planned use of laser or other hair removal procedures over HS-affected areas during the trial period.
17. Any suicidal ideation of type 4 or 5 on the C-SSRS in the past 12 months (i.e. active suicidal thoughts with method and intent but without specific plan, or active suicidal thoughts with method, intent and plan).
18. Any suicidal behavior in the past 2 years (i.e. actual attempt, interrupted attempt, aborted attempt, or preparatory acts or behavior).

19. Previous enrolment in this trial. (exception: patients re-screened).

# Study design

## Design

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| 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

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 18-08-2021 |
| Enrollment: | 3 |
| Type: | Actual |

## Medical products/devices used

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

# Ethics review

Approved WMO

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| Date: | 18-01-2021 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

Approved WMO

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| Date: | 24-04-2021 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 30-04-2021 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 15-06-2021 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 28-07-2021 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 10-08-2021 |
| 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 | EUCTR2020-003672-40-NL |
| CCMO | NL75918.100.20 |