# A Phase 2a/2b, Multicenter, Randomized, Placebo and Active Comparator-controlled, Double-Blind, Dose-ranging Study to Evaluate the Safety and Efficacy of Bermekimab (JNJ-77474462) for the Treatment of Subjects with Moderate to Severe Hidradenitis Suppurativa.

Published:
Last updated: 05-04-2024

The purpose of this study is to compare the good and bad effects of bermekimab to the good and bad effects of adalimumab and/or placebo. Adalimumab is a drug already used to treat moderate to severe hidradenitis suppurativa (HS).

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Skin and subcutaneous tissue disorders NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON49899

**Source**
ToetsingOnline

**Brief title**
LYRA

## Condition

- Skin and subcutaneous tissue disorders NEC

**Synonym**
acne inversa/ectopica - Disease of Verneuil

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Janssen-Cilag
**Source(s) of monetary or material Support:** Door de verrichter

## Intervention

**Keyword:** chronic skin disease, hidradenitis suppurativa

## Outcome measures

### Primary outcome

Percentage of Participants Achieving Hidradenitis Suppurativa Clinical

Response-50 (HiSCR50) at Week 16

### Secondary outcome

-* Proportion of participants achieving

HiSCR75 and HiSCR90 at Week 16.

-* Change from baseline in the abscess

and inflammatory nodule (AN) count

at Week 16.

-* Proportion of participants achieving

at least 50%, 75%, 90%, and 100%

reduction in total AN count at

Week 16.

-* Proportion of participants achieving an AN count of 0/1 and 0/1/2 at Week 16.

-* Proportion of participants achieving complete elimination of abscesses at Week 16 among those participants with abscesses at baseline.

-* Change in the number of abscesses from baseline to Week 16.

-* Proportion of participants achieving complete elimination of draining fistulas at Week 16 among those participants with draining fistulas at baseline.

-* Change in number of draining fistulas from baseline to Week 16.

-* Proportion of participants achieving complete elimination of inflammatory nodules at Week 16 among those participants with inflammatory nodules at baseline.

-* Change in number of inflammatory nodules from baseline toWeek 16.

-* Change ofInternational Hidradenitis

Suppurativa Severity Score System

(IHS4) score from baseline to

Week 16.

-* Proportion of participants with HSInvestigator*s

Global Assessment (HS-IGA) score of inactive (0),

almost inactive (1), or mild (2) and

with at least 2-grade improvement

relative to baseline at Week 16.

- Proportion of participants with HSIGA

score of inactive (0) or almost

inactive (1) at Week 16 among

participants with HS-IGA score of

moderate (3) or severe (4) at

baseline.

# Study description

**Background summary**

Hidradenitis suppurativa (HS) is a chronic skin disease of unclear etiology that affects 1% to 4%
of the general population. HS typically manifests as recurrent, inflamed, tender, SC nodules that are generally restricted to the
axillary, inguinal, and anogenital regions. While some nodules resolve spontaneously, others progress to form sterile abscesses, which then rupture into the skin, leading to the formation of fistulas and sinus tracts that can spontaneously release purulent drainage. Over time, chronic inflammation can lead to irreversible scarring and fibrosis, which in severe cases can result in contractures and limitations in limb mobility, especially in the axilla.

## Study objective

The purpose of this study is to compare the good and bad effects of bermekimab to the good and bad effects of adalimumab and/or placebo. Adalimumab is a drug already used to treat moderate to severe hidradenitis suppurativa (HS).

## Study design

This is a Phase 2a/2b, multicenter interventional treatment study in participants with moderate to severe HS. This study will be conducted in two parts and will enroll a target of at least 290 participants. After approximately 150 participants are enrolled in Part 1 of the study, enrollment will be paused to evaluate the data. After this evaluation, enrollment will resume, and approximately 140 participants will be enrolled into Part 2. All participants will be dosed weekly (q1w). Three doses of active treatment will be studied: Dose A, Dose B and Dose C.

## Intervention

Part 1: Part 1 will enroll approximately 150 participants. Participants will be randomized to placebo (n = 50), active comparator (n = 50), or active treatment *dose A* (n=50). At week 16 participants randomized to placebo will cross over to receive active treatment *dose A* for 16 weeks. Participants with active comparator will receive this treatment for 31 weeks. At week 16 participants randomized to active treatment *dose A* will continue active treatment *dose A* for an additional 16 weeks. All subjects will be followed for an additional 5 weeks of safety follow-up.

Part 2: Part 2 will be initiated after week 16 of Part 1 interim analysis is completed. Approximately 140 patients will be enrolled in Part 2. Participants will be randomized to receive placebo (n=20), active comparator (n=20), active treatment *dose A* (n=20), active treatment *dose B* (n=40), or active treatment *dose C* (n = 40). At week 16 participants randomized to placebo will cross over to receive active treatment *dose A* for 16 weeks. Participants with active comparator will receive this treatment for 31 weeks. At week 16, participants randomized to active treatment *dose A*, *dose B* or *dose C* will continue their respected dose regimens for an additional 16 weeks. All participants will be followed for an additional 5 weeks of safety follow-up.

## Study burden and risks

Potentially unknown discomfort, adverse events and risks are linked to the use of the investigational product. It is possible that during the study newinformation is brought to the attention of the sponsor regarding the disease, investigationa product and the risks. If this is the case, the investigator and his team will inform the patient in a timely manner. This new

information can potentially change the mind of the patient to continue his/her trial participation.

# Contacts

**Public**
Janssen-Cilag

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**Scientific**
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NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

- Have hidradenitis suppurativa (HS) for at least 1 year (365 days) prior to the baseline visit as determined by the investigator through participant interview and/or review of the medical history
- Have Hurley Stage II or Hurley Stage III HS as determined by the investigator at screening and baseline visits
- Have HS lesions present in at least 2 distinct anatomic areas (examples include but are not limited to left and right axilla; or left axilla and left inguinocrural fold) at screening
and baseline visits

- Have a total abscess and inflammatory nodule (AN) count of greater than or equal to (>=)5 at the screening and baseline visit
- Agree not to receive a live virus or live bacterial vaccination during the study and for 90 days after the last administration of study intervention

### Exclusion criteria

- Has a current diagnosis or signs or symptoms of severe, progressive, or uncontrolled renal, cardiac, vascular, pulmonary, gastrointestinal, endocrine, neurologic, hematologic, rheumatologic, psychiatric, or metabolic disturbances
- Has unstable cardiovascular disease, defined as a recent clinical deterioration (that is, unstable angina, rapid atrial fibrillation) in the last 3 months or a cardiac hospitalization within the last 3 months
- Has or has had herpes zoster within the 2 months before screening
- Has a transplanted organ (with exception of a corneal transplant greater than [>]3 months before the first administration of study intervention)
- Has known allergies, hypersensitivity, or intolerance to bermekimab or adalimumab or its excipients

## Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Enrollment: | 5 |
| Type: | Anticipated |

## Medical products/devices used

| | |
|---|---|
| Generic name: | FibroTx T Patch |
| Registration: | No |
| Product type: | Medicine |
| Brand name: | Humira |
| Generic name: | Adalimumab |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | JNJ-77474462 |
| Generic name: | Bermekimab |

# Ethics review

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|---|---|
| Approved WMO Date: | 28-10-2021 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 13-12-2021 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 18-03-2022 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 18-06-2022 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 05-08-2022 |
| Application type: | Amendment |

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| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |

# 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 | EUCTR2020-002607-19-NL |
| ClinicalTrials.gov | NCT04988308 |
| CCMO | NL78515.056.21 |