Study background

HS is a chronic inflammatory skin condition that causes recurrent, painful skin lesions in areas where skin rubs together, like the armpits, groin, and under the breasts. These lesions can become inflamed, filled with pus, or have a foul odor, and they may also cause scarring. HS is not contagious, but it may be painful. Many people don't respond to current therapies, and there is a large need for new treatment options.

What is the purpose of the CEDAR Study?

The purpose of this study is to evaluate the study drug for efficacy and safety in HS.

Researchers are interested in learning whether the study drug

- Improves the lesions caused by HS.
- Is safe and well-tolerated with long-term use.

Welcome to the CEDAR Study!

We are so happy you have decided to join the CEDAR Study. Your help will be invaluable to so many, including doctors, researchers, and the entire HS community.

This research study is being done to learn more about a potential new oral drug for HS. This brochure describes the study and answers common questions about what's involved. The study team is happy to answer any additional questions you have.

It is with the help of volunteers like you that researchers are able to bring new treatments to those who need them.

With much appreciation,
The CEDAR Study Team

Study contact information:

Name: _____

Phone number: _____

Email: _____

Scan the code or visit **www.InsmedCedarStudy.com**.
PIN: **1007**

This clinical study is conducted and funded by Insmed Incorporated.

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The CEDAR Study

A clinical research study to evaluate an oral study drug for hidradenitis suppurativa (HS)

What is the study treatment?

The study treatment is a tablet taken orally (by mouth) once a day. During Study Treatment Period 1, you will receive either the active study drug or the placebo. The placebo looks just like the study drug but contains no active ingredients. During Study Treatment Period 2, all participants will receive the active study drug at different doses. Neither you nor the study doctor will know which study treatment or dose you will receive.

Study Treatment Period 1

Study Treatment Period 2

What happens during the study?

The study lasts about 15 months (around 60 weeks) with 20 planned clinic visits. The study has 4 periods: a Screening Period, 2 Study Treatment Periods, and a Follow-up Period.

Screening Period — 1 visit to check eligibility

Study Treatment Period 1 — Clinic visits every 2 weeks for 16 weeks

Study Treatment Period 2 — Clinic visits every 4 weeks for 36 weeks

Follow-up Period — 1 clinic visit 4 weeks after stopping the study treatment

During the study, the use of certain analgesic (painkiller) medicines taken for HS-related pain will be recorded every day in an electronic diary (eDiary).

What tests will I have?

Inside this brochure is an overview of the study design and a summary of tests to expect during clinic visits. Speak with the study doctor to learn more.

Important reminders

- Follow the study staff's instructions.
- Attend all study visits.
- Answer questionnaires completely and to the best of your ability.
- Complete the dosing diary.
- Record the use of certain analgesic (painkiller) medicines taken for HS-related pain every day in an eDiary.
- Stay in touch with your study team.

Please scan the QR code below for info sliders that will guide you on how to make the most of your experience.

The CEDAR Study Overview

Study treatment

Screening Period
(up to 31 days)

Adults who have been diagnosed with moderate to severe HS for at least 6 months

1 clinic visit

Study Treatment Period 1
(16 weeks)

Study drug (brensocatib)

Placebo

Clinic visits every 2 weeks

Study Treatment Period 2
(36 weeks)

Study drug (brensocatib)

Clinic visits every 4 weeks

Follow-up Period
(4 weeks)

No study treatment

1 clinic visit

Health checks and tests

Screening Period
- Medical and surgical history
- Medicine review
- Physical exam
- Blood sample
- Pregnancy test (if applicable)
- Urine sample
- Heart activity (ECG)
- Vital signs
- HS disease assessment
- Assessment of skin pain

Study Treatment Period 1 and Study Treatment Period 2
- Medical and surgical history
- Medicine review
- Physical exam
- Blood sample
- Pregnancy test (if applicable)
- Urine sample
- Heart activity (ECG)
- Vital signs
- Study treatment dispensed and given
- Checking unused study treatment
- Complete eDiary
- HS disease assessment
- Assessment of skin pain
- Side effects check
- Questionnaires
- Tissue sample for PD substudy (optional, US only)

Follow-up Period
- Medicine review
- Pregnancy test (if applicable)
- Vital signs
- Side effects check
- HS disease assessment
- Assessment of skin pain
- Questionnaires
- Complete eDiary

You will not have every test at each visit.

Glossary

Assessment of skin pain: Through your eDiary you will be asked to assess your skin pain daily on an 11-point scale with 0 being "no pain" and 10 being the "worst imaginable pain."

Blood sample: Blood samples will be taken from a vein, usually in the arm, to check on your general health and how different parts of your body are working. The levels of the active study drug in your blood over time and how your body may be responding to it will also be measured.

Heart activity (ECG): The electrical activity of your heart will be measured using a painless test called an electrocardiogram (ECG). For this test, you will lie down and small sticky pads will be attached to your skin. The pads are connected by wires to a computer that will pick up signals every time your heart beats.

HS disease assessment: The study doctor will examine your skin and record the location, type, count, and severity of your HS lesions.

Medical and surgical history: The study staff will ask about your current and past health, including any surgeries you may have had.

Medicine review: The study staff will ask questions about medicines you are taking now or have taken in the past.

Physical exam: The doctor will check your overall health by examining your body, including your general appearance, head, eyes, ears, nose, mouth, skin, abdomen, hands, and feet. The doctor will listen to your heart and lungs.

Pregnancy test: Participants who are able to have children will have their blood or urine tested for pregnancy throughout the study.

Questionnaires: You will answer questions about your health, how you are feeling, and how your condition affects your everyday life.

Side effects check: Your health will be continuously monitored for any side effects, which are unwanted or undesired effects from the study treatment.

Tissue sample for pharmacodynamics (PD) substudy (optional, US only): This substudy in the United States will help us explore the effect of the study drug on your HS lesions. A tissue sample from your HS lesion will be collected via punch biopsy for this analysis. You may be asked to sign a separate consent form to allow collection of your tissue sample.

Urine sample: You will be asked for a urine sample in a cup for laboratory testing.

Vital signs: These measurements include your body temperature, heart rate (how fast your heart beats), breathing rate (how many breaths you take in 1 minute), and blood pressure (how the heart pumps blood through the blood vessels).