Facing

hidradenitis suppurativa

together

Participant Study Guide

The LOTUS Study

LOTUS

Study facts at a glance

PARTICIPATION TIME
Up to 24 weeks (about 6 months)

STUDY CENTER VISITS
12 visits

PEOPLE TAKING PART
Approximately 180 people

PARTICIPATING STUDY CENTERS
Approximately 100

PARTICIPATING REGIONS
Taking place globally

Welcome!

Thank you for agreeing to take part in the **LOTUS Study**.

We are grateful to have you on board as a participant. While you may not experience any benefit from taking part in this study, your decision to join may help advance medical knowledge and may help in the development of better treatments for hidradenitis suppurativa (HS) in the future.

Our experienced team is here to provide you with the highest standard of care and will do everything possible to ensure your safety and well-being throughout the study. We appreciate your commitment and trust in our work, and we look forward to partnering with you in this important endeavor.

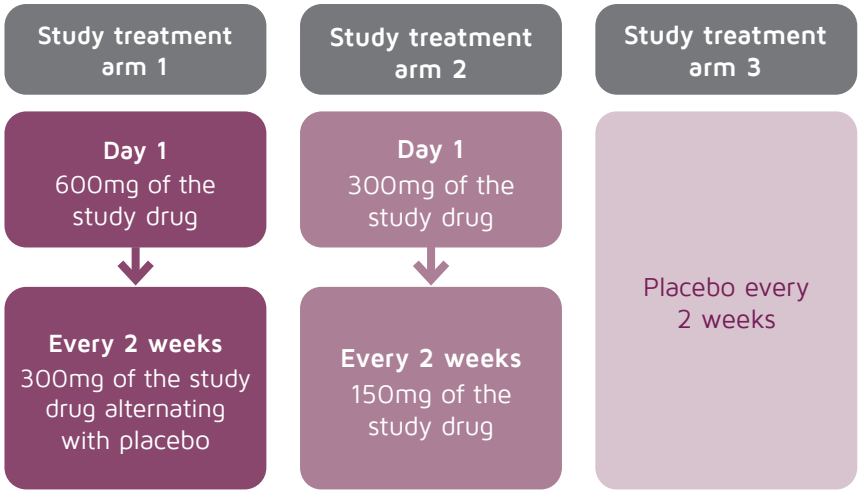
Thank you for being such a vital part of our research community and for leading the way for other people with HS.

The LOTUS Study Team

Study design

Dose selection

You will be randomly assigned, like flipping a coin, to one of three study treatment arms and receive either the investigational study drug or placebo. A placebo is an inactive substance sometimes given to participants in a research study; it looks like the study drug but will not have any effect on the medical condition being studied. Throughout this guide, "study treatment" refers to either the study drug or placebo.



You will have a 67% (2 in 3) chance of receiving the study drug.

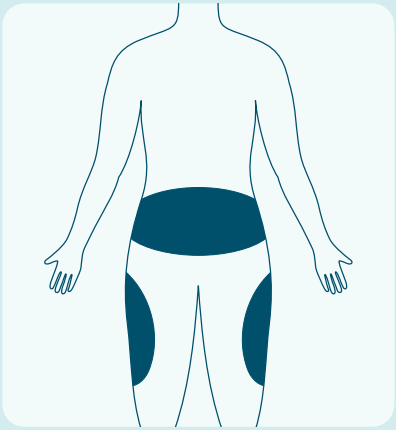
As there is a difference in both the dosing schedule (study treatment arm 1 is every 4 weeks; study treatment arm 2 is every 2 weeks), as well as the dose of study drug, participants assigned to either study treatment arm 1 or study treatment arm 2 will receive a combination of active study drug and placebo. This is done so that:

- Everyone receives the same number of injections at each visit.
- Neither you nor your study doctor know what study treatment you are receiving (this is called "**double blind**").

This means **all participants will receive study injections every 2 weeks** (which could be placebo, active study drug, or a combination of placebo and active study drug, depending on the study treatment arm and study week).

"Double-blind" study treatment ensures that the study results are treated in exactly the same way, without any intended or unintended bias. In the event of a medical emergency, the study doctor will be able to find out which study treatment you have received.

Receiving the study treatment



The study drug or the placebo will be given to you as a subcutaneous injection. This means an injection just under the skin in either your abdomen (stomach area) or thigh. Depending on the visit, you will receive either one, two, or four separate injections.

You will need to stay at the study center for 1 hour after the first dose of study drug, and for 30 minutes after all other doses. This is for your safety, so the study team can check on you. There might be some swelling or slight bruising after you have the study injections.

Speak to the study team if you are worried about injections or needles.

Other study commitments

You will be required to keep an electronic diary as part of the study. You will start this diary 7 to 14 days before the day of your first study injections and continue through your end of study treatment visit at Week 16.

A member of the study team will show you how to complete the diary.

You will access the diary through an app on a mobile device (either your own, or one lent to you by the study team for the length of the study).

You will be asked to assess any HS-related pain, and any pain medications you use for your HS pain.

You should record your entries every day at approximately the same time each day.

Your diary entries will be reviewed by the study team between and/or during your study center visits.

The diary entries are important – the daily assessments will help show whether your assigned study treatment is having any effect on your HS symptoms.

Study tests

The following tests and assessments will occur during the study (not all tests/assessments will take place at every visit):

Provide personal information, such as your age, race, gender, and ethnicity

Answer questions about your medical history and your HS

Answer questions about current and previous medications you are or have been taking, including medications for HS

Measure your height

Perform a physical examination, including measurement of your weight

Collect blood and urine samples to test for pregnancy and your ability to become pregnant (if appropriate)

Collect blood samples to test for infections, monitor your safety and measure how the study drug is affecting your body

Measure your blood pressure, heart rate, and body temperature – these are called vital signs

Record the rate and rhythm of your heart beats – this is called an electrocardiogram

Perform a chest x-ray to make sure you do not have a chest infection, especially tuberculosis

Complete questionnaires about how HS is affecting your life

Assess the severity of your HS by examining your skin

Assess whether there have been any changes in your health since the last visit

If applicable, discussions on the importance of using contraception throughout the study, and for 14 weeks after your last dose of study treatment

You are free to leave the study at any time and for any reason. If you leave the study before the end of the study treatment period, you will be asked to attend an early termination visit as well as a safety follow-up visit 6 weeks after your last dose of study treatment. At these visits, you will have tests performed so that we can check on your health and well-being.

Reminders

Please **fill in your electronic diary every day**, at around the same time each day.

If applicable, please use contraception throughout the study **and for at least 14 weeks after your final study injection**. The study doctor will advise you on whether contraception is required for you, and if so, which methods are acceptable. Please tell the study doctor immediately if you become pregnant.

Please let the study team know if you will not be able to attend a study center visit so it can be rearranged.

Please let the study team know as soon as possible if you notice any changes to your health or are concerned about anything.

You may be reimbursed for your travel expenses during your study participation – the study team will be able to tell you more.

Notes