

Summary of Clinical Trial Results

For Laypersons



A study to learn how effective and safe the study drug adalimumab is for patients with hidradenitis suppurativa

Overall Summary

- Hidradenitis suppurativa (HS) is a long-lasting inflammatory disease of the skin that causes redness, swelling, or lumps (lesions) in the skin where oil and sweat glands are located or the skin rubs together such as the armpit, groin, or anal and genital regions.
- The main aim of this study was to reduce patient's HS symptoms.
- In this study, doctors (investigators) tested the study drug adalimumab in patients who had HS for at least one year and had at least 3 different locations on their body with active HS lesions, of which one would require surgery to remove.
- Patients were randomly separated into 2 groups by a computer program. One group was given study drug and the other group was given placebo (looks like study drug but contains no medicine).
- After 12 weeks of treatment, study doctors looked at how the patients' HS signs and symptoms changed when compared to their HS signs and symptoms before treatment.
- Around 70% of patients in both groups had side effects.
- The most common side effects for patients taking adalimumab were nasopharyngitis (common cold), procedural pain (pain from surgical procedure), worsening of hidradenitis, headache, diarrhea, and arthralgia (joint pain).
- The most common side effects for patients taking placebo were nasopharyngitis (common cold), worsening of hidradenitis, headache, surgical procedural pain, and dizziness.
- If you participated in this study and have questions about your individual care, contact the doctor or staff at your study site.

1. General information about the study

1.1 Why was this study done?



Researchers are looking for a better way to treat hidradenitis suppurativa (HS). HS is a long-lasting inflammatory disease of the skin that causes redness, swelling, or lumps (lesions) in the skin where oil and sweat glands are located or where the skin rubs together. Common locations on the body are the armpits, groin, or anal and genital regions. Women are affected by HS 2 to 5 times more commonly than men. Factors that may increase risk of HS include genetics, smoking, and obesity.

The medicines used to treat HS do not work the same for all patients. Symptoms do not improve for some patients despite treatment. Because of this, researchers are looking for different medicines to treat these patients.

In this study, the study doctors used a medicine called adalimumab. Adalimumab works to control the activity of the immune system to help patients with inflammatory diseases, like HS.

The main aim of the study was to find out if adalimumab helped to lessen the signs and symptoms of HS compared to placebo (no medicine) after the first 12 weeks of treatment.

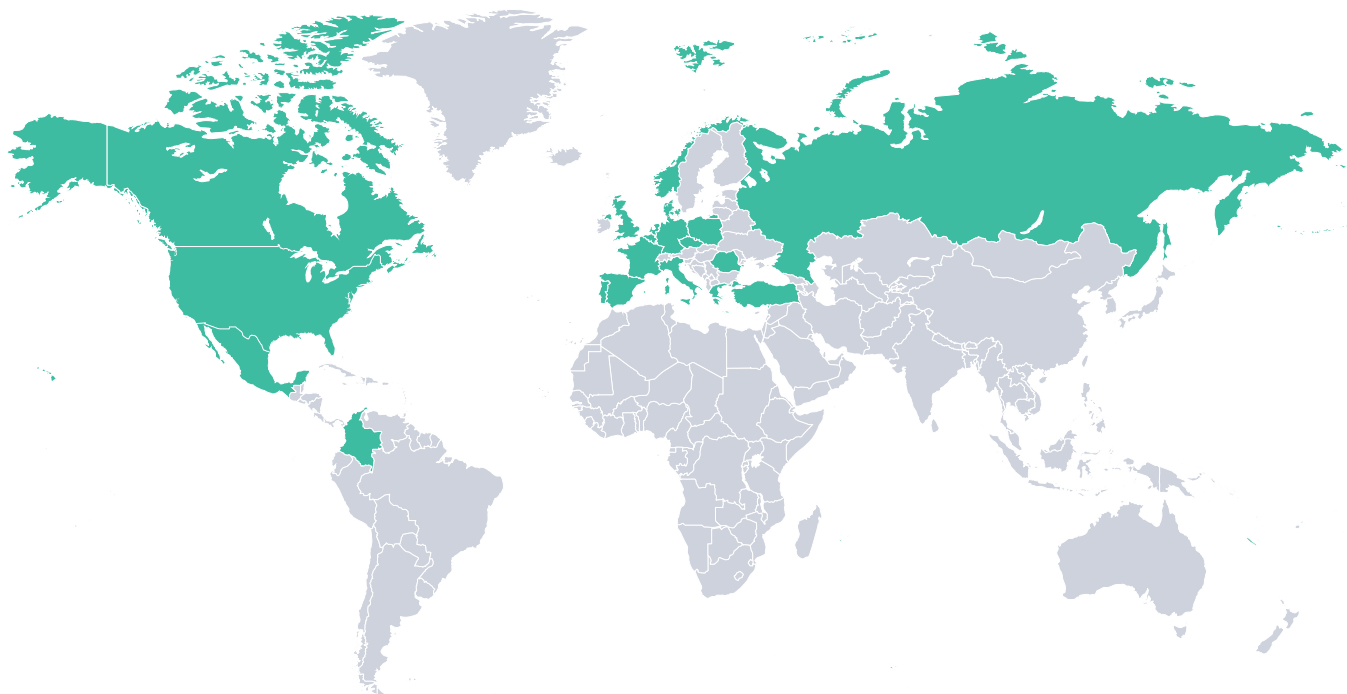
Researchers have tested this medicine in many studies of people with different inflammatory diseases. Adalimumab has been approved to treat different inflammatory diseases including HS. Phase 4 studies test treatments that have already been approved to treat patients with a condition or disease.

In this Phase 4 study, the study doctors continued testing the benefits of adalimumab in patients with HS. The study doctors also looked for any side effects patients may have had after starting treatment with adalimumab. This study was “double-blinded”, which means that neither the patients nor the study doctors knew who was given which study drug (adalimumab or placebo). This helps ensure that study results are not influenced.

This summary only includes the results from this study, which may be different from the results of other studies.

1.2. When and where was the study done?

This global study took place from July 2016 to October 2019 in the following countries: Belgium, Canada, Colombia, Czechia, Denmark, France, Germany, Greece, Italy, Mexico, The Netherlands, Norway, Poland, Portugal, Romania, Russia, Spain, Turkey, United Kingdom, and United States.

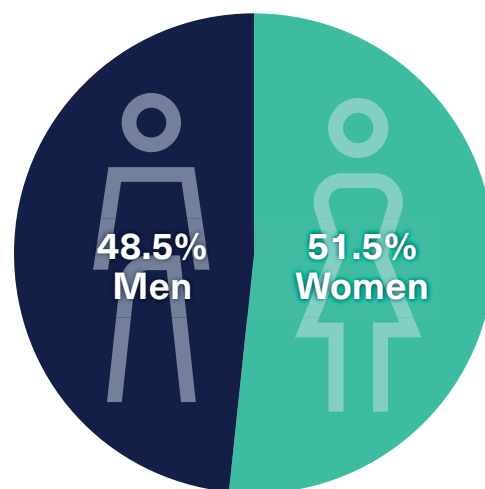


2. What patients were included in this study?

A total of 206 adult patients diagnosed with HS took part in the study. Of the 206 patients, 165 completed the study and 41 did not: 17 patients left the study by personal choice, 10 patients were lost to follow-up (did not return to continue treatment or testing), 7 patients left the study because of side effects, 6 left for other, unknown reasons, and 1 patient had HS surgery earlier than planned.

All the patients had confirmed HS for at least one year with 3 separate areas on the body with active HS lesions that would require surgery to remove.

There were approximately the same number of women (51.5% of patients) and men (48.5% of patients) in the study.



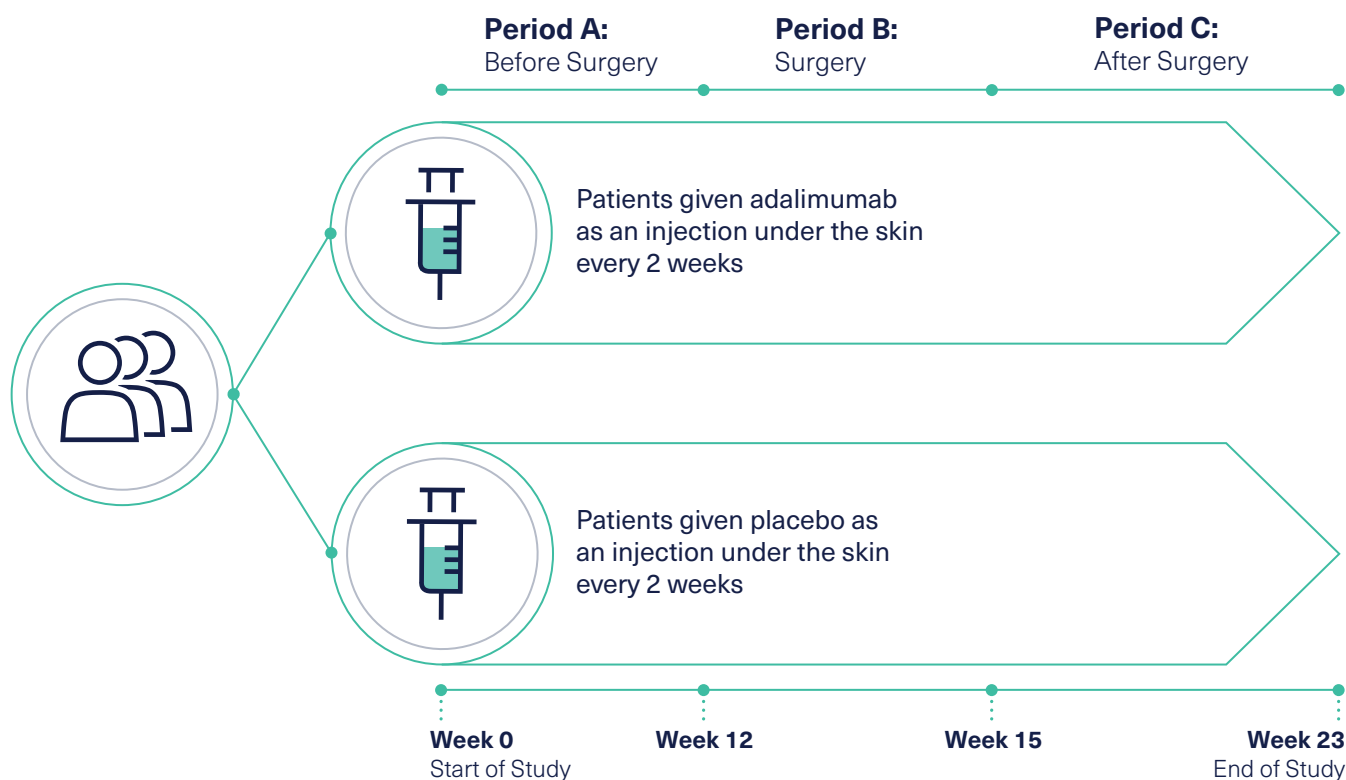
3. Which medicines were studied?

The medicine in this study was called adalimumab. At the beginning of the study, a computer program was used to randomly (by chance) put the patients into 1 of 2 groups. This process is called “randomization”, which helps make the groups equal and reduces differences between groups. Randomization allows the results of each treatment to be compared as accurately as possible. In this study, one group was given adalimumab and one group was given placebo. A placebo looks like the treatment medicine but has no active drug in it.

Neither the patients nor the study doctors knew what patients were given adalimumab and what patients were given placebo.

The study included 3 parts. In Period A, patients were given adalimumab or placebo as an injection under the skin for 12 weeks. After 12 weeks of treatment, study doctors looked at how the patient’s HS signs and symptoms changed when compared to their HS signs and symptoms before treatment. They compared results from patients who were given adalimumab to patients given placebo. In Period B, patients underwent surgery to remove active HS in one area while still receiving adalimumab or placebo as started in Period A. In Period C, patients continued with adalimumab or placebo as an injection under the skin as started in Period A.

The diagram below shows how the study was organized.



4. What were the side effects?

Side effects are unwanted medical events that happen during a study. They may or may not be caused by the treatment in the study.

A side effect is serious if it leads to death, is life-threatening, puts a patient in the hospital, keeps a patient in the hospital for a long time, or causes a disability that lasts a long time.

Related side effects are side effects that were considered by the study doctor to be at least possibly related to study drug.

7 patients treated with adalimumab (6.8% of patients) and 3 patients treated with placebo (2.9% of patients) had serious side effects during the study. The total number of patients treated with adalimumab that had serious side effects considered possibly related to the study drug was 1 patient (1.0% of patients). None of the serious side effects in patients treated with placebo were considered possibly related to the study drug.

3 patients treated with adalimumab (2.9% of patients) and 4 patients treated with placebo (3.9% of patients) stopped taking the study drug because of side effects during the study. The total number of patients treated with adalimumab or placebo that stopped taking the study drug because of side effects considered possibly related to the study drug was 2 patients in each group (1.9% of patients each group).

1 patient died during the study from brain hemorrhage and 1 patient died after the completion of the study from natural causes. Neither deaths were considered possibly related to study drug.

The table below shows information about the patients who had related serious side effects in the study, and the patients who had related side effects that led to stopping study drug, and related side effects leading to death.

	Placebo (103 Patients)	Adalimumab (103 Patients)
Number of patients with related serious side effects	0 (0.0% of patients)	1 (1.0% of patients)
• Blastocystis infection (parasite living in gastrointestinal tract)	0 (0.0% of patients)	1 (1.0% of patients)
Number of patients who stopped taking study drug because of related side effects	2 (1.9% of patients)	2 (1.9% of patients)
• Blastocystis infection	0 (0.0% of patients)	1 (1.0% of patients)
• Headache	0 (0.0% of patients)	1 (1.0% of patients)
• Hidradenitis suppurativa	1 (1.0% of patients)	0 (0.0% of patients)
• Dizziness, chest pain, increased creatine kinase (CK) protein in blood, myopathy (muscle weakness)	1 (1.0% of patients)	0 (0.0% of patients)
Number of related side effects leading to death	0 (0.0% of patients)	0 (0.0% of patients)

74 patients treated with adalimumab (71.8% of patients) and 69 patients treated with placebo (67% of patients) had side effects during the study. The total number of patients that had side effects considered possibly related to the study drug was 36 patients treated with adalimumab (35% of patients) and 26 patients treated with placebo (25.2% of patients).

The table below shows information about the common related side effects (in at least 3 or more patients in either group) in this study. The most common related side effects were nasopharyngitis (common cold), injection site pain, and headache.

	Placebo (103 Patients)	Adalimumab (103 Patients)
Number of patients with at least one related side effect	26 (25.2% of patients)	36 (35% of patients)
Common related side effects (Related side effects occurring in at least 3 patients)		
• Nasopharyngitis	1 (1.0% of patients)	8 (7.8% of patients)
• Injection site pain	5 (4.9% of patients)	3 (2.9% of patients)
• Headache	5 (4.9% of patients)	4 (3.9% of patients)
• Injection site reaction	2 (1.9% of patients)	3 (2.9% of patients)
• Dizziness	3 (2.9% of patients)	1 (1.0% of patients)
• Hidradenitis	2 (1.9% of patients)	3 (2.9% of patients)

5. What were the overall results of the study?

The study was completed as planned. The study doctors found that the patients who had taken adalimumab had fewer signs and symptoms of HS after 12 weeks of treatment compared to patients who had taken placebo.

Signs and symptoms of HS were based on the patient's hidradenitis suppurativa clinical response score (HiSCR) which looked at the number of active HS lesions after 12 weeks of treatment to the number of HS lesions before treatment. The HiSCR score defines a clinical response as patients having a decrease of 50% or more in the number of existing HS lesions and no appearance of new HS lesions compared to before the start of treatment.

Patients who were given adalimumab had better clinical response at Week 12 than patients given placebo. 49 patients (47.6% of patients) given adalimumab achieved clinical response based on HiSCR at Week 12 compared to 35 patients (34% of patients) given placebo.

6. How has the study helped patients and researchers?

This study showed that adalimumab is safe and effective for patients with HS and can be used alongside surgery as a treatment option for patients.

This summary only shows the results from this study, which may be different from the results of other studies.

7. Are there any plans for future studies?

A study of the long-term safety and efficacy of adalimumab in patients with HS in Japan is ongoing.

8. Who sponsored this study?

This study was sponsored by AbbVie. This summary was reviewed for readability by a patient advocacy group.

9. Where can I find out more information about this study?

Title of Study	A Phase 4, Double-Blind, Randomized, Placebo-Controlled Multicenter Study to Assess the Safety and Efficacy of Adalimumab Used in Conjunction with Surgery in Subjects with Moderate to Severe Hidradenitis Suppurativa
Protocol Number	M15-574
Clinicaltrials.gov	NCT02808975 https://clinicaltrials.gov/ct2/show/NCT02808975?term=M15-574&draw=2&rank=1
EudraCT	2015-005161-23 https://www.clinicaltrialsregister.eu/ctr-search/search?query=2015-005161-23
Study Sponsor	AbbVie Phone: +1 800-633-9110 Email: abbvieclinicaltrials@abbvie.com



Thank You

AbbVie wants to thank all the participants for their time and effort that went into making this study possible.

Clinical study participants help advance science!

