NOVARTIS

Clinical Trial Results Summary

A Study to Learn About the Effects of AIN457 in People With Hidradenitis Suppurativa (HS)

Thank you!

Thank you to the participants who took part in the clinical trial for Hidradenitis Suppurativa. Every participant helped the researchers learn more about **AIN457**, also called secukinumab.

Novartis sponsored this trial and believes it is important to share what was learned from the results of this trial with the participants and the public.

We hope this summary helps the participants to understand their important role in medical research.

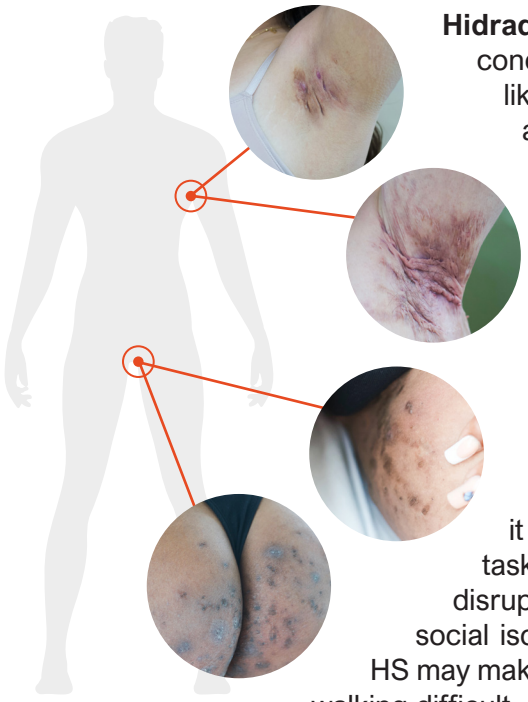
Trial information

Trial number: CAIN457M2301 (SUNSHINE)
Drug studied: AIN457 (secukinumab)
Sponsor: Novartis

If you were a participant and have any questions about the results, please talk to the doctor or staff at the trial site.

This summary only shows the results of a single clinical trial. Other clinical trials may have different findings.

What was the main purpose of this trial?



Hidradenitis suppurativa (HS) is a long term and painful skin condition. It causes deep, painful bumps in areas with hair follicles, like the underarms, breasts, buttocks, and groin. They may start as small bumps or nodules under the skin. Over time, they become swollen and red. The nodules may fill with pus and become **abscesses**. These abscesses can burst, leaving open wounds and causing tunnels under the skin. The tunnels and abscesses may drain fluid which often has a bad smell. These open wounds often do not heal by themselves and may become infected. Long-lasting wounds may lead to scarring.

HS worsens quality-of-life, making it hard for people to do everyday tasks. Work and social life is usually disrupted. This could lead to sadness, social isolation, and depression. Symptoms of HS may make even basic activities such as sitting and walking difficult.

Drug
secukinumab

Pronounced as
se-koo-KI-noo-mab

Currently, there are few effective treatments for HS. Antibiotics can help temporarily, but they may cause stomach problems and may make future infections harder to treat. Other treatments for HS may not work in all people with HS, and if they do, the symptom relief may not last for very long. As a result, there is a need for other safe and effective treatments for HS.

Researchers wanted to learn more about a drug called **AIN457 (secukinumab)** and whether it is effective in treating people with HS. AIN457 is currently approved to treat plaque psoriasis, as well as other conditions. Earlier research has shown that AIN457 may also help treat HS.

AIN457 is a type of antibody made in labs and can be used to treat illnesses**.** Antibodies are normally made by the body's immune system to fight infections.

In this trial, researchers wanted to learn about the effects of the trial drug AIN457 in participants with moderate to severe HS.

The main questions that researchers wanted to answer were:

- How many participants' HS improved after 16 weeks of treatment?
- What adverse events did participants have during this trial?
  - ↳ An **adverse event** is any sign or symptom that participants have during a trial.

Photo Credits: HSConnect.org/hs-image-library

How long was this trial?

The trial began in January 2019 and ended in July 2022. The entire duration was about 3 and a half years. The trial was designed so that each participant would participate in the trial for up to 64 weeks.

When the trial ended, researchers created a report of the trial results. This summary is based on that report.

Who was in this trial?

541 participants with moderate to severe HS received treatment in this trial. Participants' ages ranged from 18 to 73 years. Their average age was 36 years.

The number of participants by gender and race are shown below.

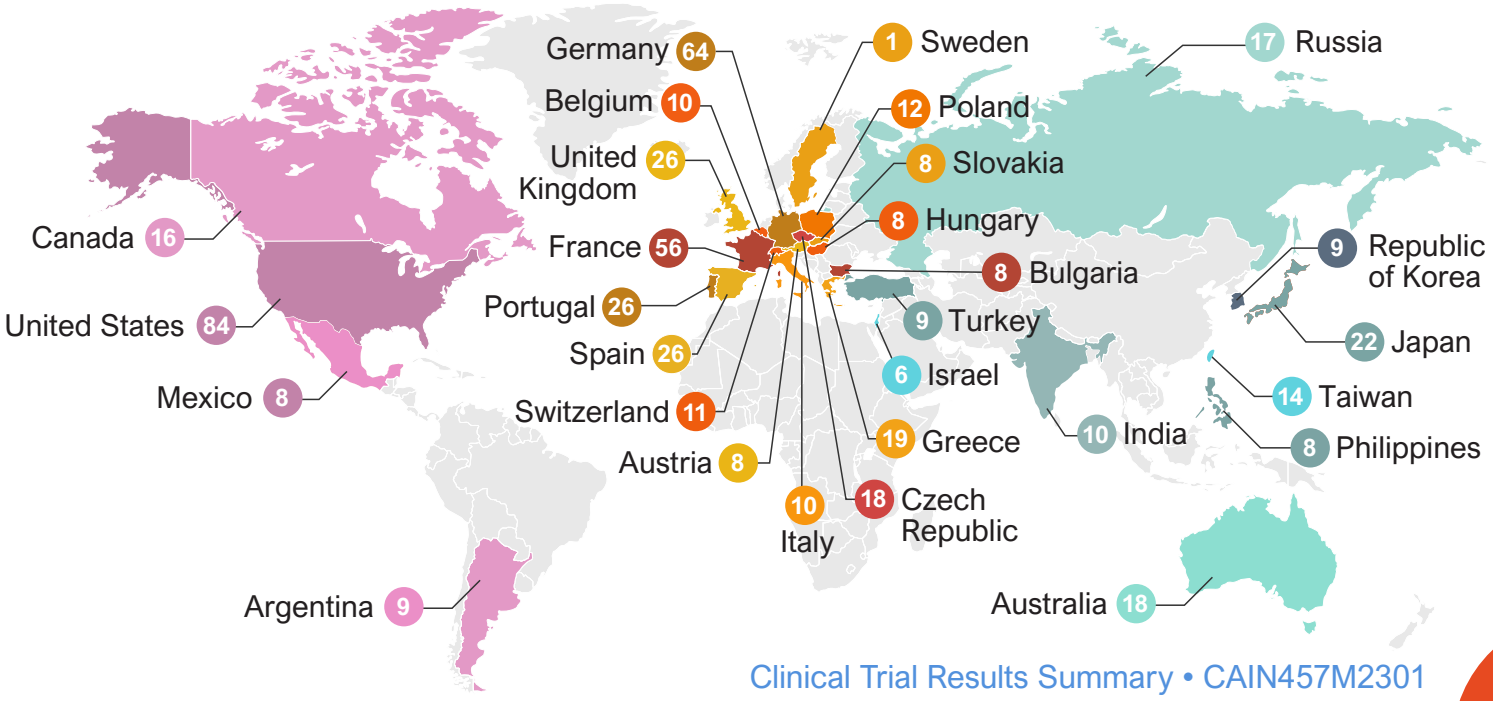
Gender

237 Men	304 Women

Race

430 White	37 Black or African American	66 Asian
4 American Indian or Alaska Native	4 Multiple Races	

541 participants from **29 countries** received treatment. The map below shows the number of participants who took part in each country.



Participants **could take part** in this trial if they:

- Had a diagnosis of HS for at least 1 year prior to their first trial visit.
- Had moderate to severe HS which was defined as:
  - Having 5 or more nodules or abscesses,

  and
  - Having nodules or abscesses in at least 2 distinct areas of the body
- Agreed to use antibacterial products daily while being treated with trial drug.

Participants **could not take part** in this trial if they:

- Had other active skin diseases or recent infections.

What treatments did the participants receive?

Researchers studied the following treatments:

AIN457: 300 milligrams (mg), given as an injection under the skin, every 2 or 4 weeks.

Placebo: Looks like the trial drug but does not have any active drug in it. Researchers compared treatment with AIN457 to placebo. Using a placebo helps researchers better understand and confirm the effect of the trial drug.

Participants were randomly assigned to 1 of 4 treatment groups by a computer. In this trial, none of the participants, trial doctors, or trial staff knew what treatments the participants were receiving. Doing a trial this way helps to make sure that the results are looked at with fairness across all treatments.

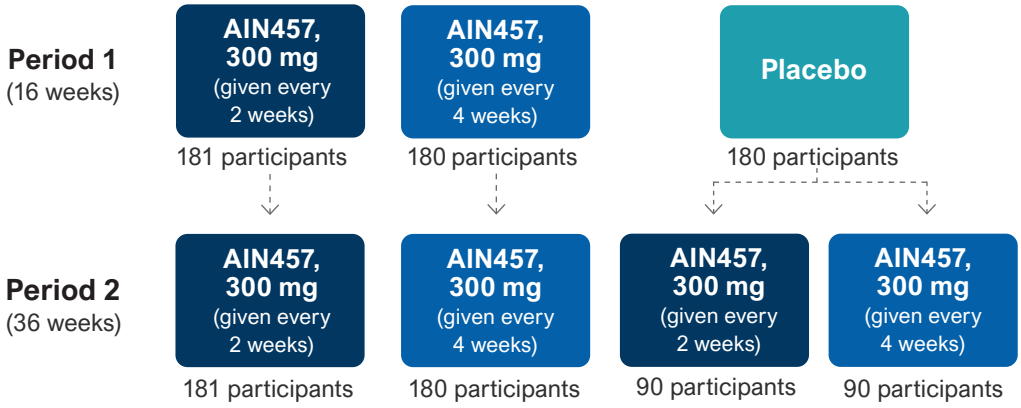
What happened during this trial?

Before treatment — Up to 4 weeks

At the start of the trial, all participants were checked to make sure they could take part. Trial doctors performed physical exams, blood tests, urine tests, and asked participants questions about their medical history.

During treatment — 52 weeks (1 year)

The trial had 2 periods. **Period 1** lasted up to 16 weeks. **Period 2** was 36 weeks.



All participants received AIN457 300 mg during Period 2.

During the first 4 weeks of each Period, participants received treatment once a week. Doing this helps the trial drug reach effective amounts in the body faster.

After 16 weeks of treatment, Period 1 was complete and researchers were able to answer the main question of the trial.

Participants continued to be treated through Period 2, which lasted an additional 36 weeks. This was up to 52 weeks from the start of treatment. Researchers wanted to know if the treatments were safe and easy to tolerate and whether they would continue to provide benefit to participants.

After treatment — 8 weeks

Participants had a follow-up visit 8 weeks after their last dose of treatment.

Trial doctors continued to check HS symptoms and record medical problems.

Participants who **completed Period 2** were given the option to continue treatment in a separate extension trial, CAIN457M2301E1.

What were the main results of this trial?

How many participants' HS improved after 16 weeks of treatment?

- A higher percentage of participants responded to treatment in both the **AIN457 given every 2 weeks** group and **AIN457 given every 4 weeks** group compared to the placebo group.
- Researchers considered the difference between the **AIN457 given every 2 weeks** group and the placebo group to be meaningful.
- However, this could not be demonstrated for the **AIN457 given every 4 weeks** group.

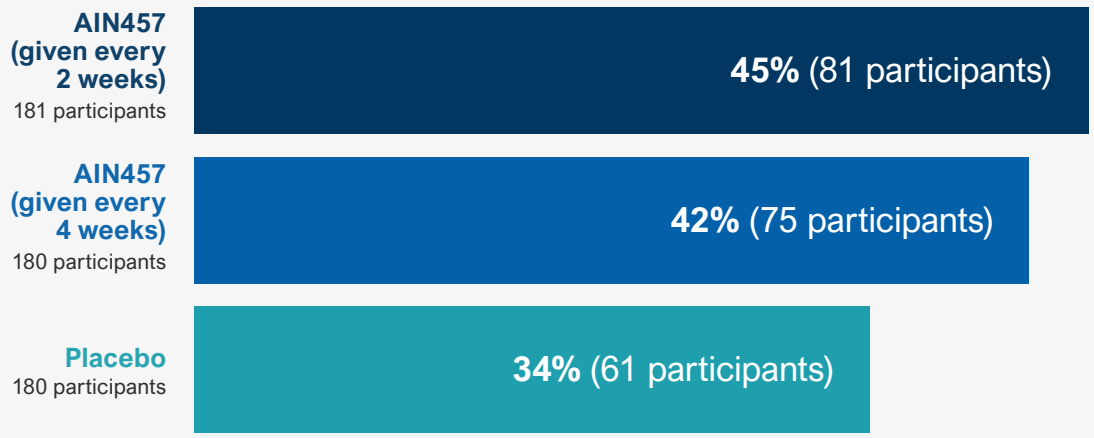
Researchers wanted to know how many participants had a Hidradenitis Suppurativa Clinical Response (HiSCR) after 16 weeks of treatment with AIN457. In this trial, a participant was considered to have responded to treatment if they:

- Had at least a 50% decrease in abscesses and nodules
- Had no new abscesses
- Had no new draining tunnels, also known as **draining fistulas**

What is a fistula?
A fistula is a tunnel that forms within the body tissue, allowing fluids like pus and blood to drain where they normally would not. In more severe forms of HS, fistulas can form between areas that are affected by nodules or abscesses.

The results are given below:

Percentage of participants who achieved HiSCR



What were the other results of this trial?

How many participants had an increase in HS symptoms, also called HS flare, during the first 16 weeks of treatment?

During Period 1:

- **AIN457 given every 2 weeks:** 28 out of 181 participants (15%) had HS flares.
- **AIN457 given every 4 weeks:** 42 out of 180 participants (23%) had HS flares.
- **Placebo:** 52 out of 181 participants (29%) had HS flares.

In this trial, an HS flare was defined as an increase in the number of abscesses or nodules by 25% or more since the first study visit

How many participants had at least a 30% decrease in skin pain after 16 weeks of treatment?

After Period 1:

- **AIN457 given every 2 weeks:** 45 out of 131 participants (34%) had decreased pain.
- **AIN457 given every 4 weeks:** 40 out of 123 participants (32%) had decreased pain.
- **Placebo:** 28 out of 119 participants (24%) had decreased pain.

Participants recorded how much pain they felt every day in an electronic diary.

What adverse events did the participants have?

Medical problems that happen in clinical trials are called **adverse events**.

A lot of research is needed to know whether a drug causes an adverse event. When new drugs are being studied, researchers keep track of all adverse events participants have, whether or not they are thought to be caused by the trial treatment.

This section is a summary of the adverse events that happened up to 8 weeks after the last day of trial drug.

An **adverse event** is:

- Any **sign or symptom** that the participants have during a trial
- Considered **serious** when it is life-threatening, causes lasting problems, the participant needs hospital care, or results in death

Adverse events **may** or **may not** be caused by treatments in the trial.

How many participants had adverse events?

The table below is a summary of the adverse events that participants had throughout the trial.

The Placebo column only includes adverse events that happened during Period 1 since all participants were taking AIN457 during Period 2.

The **Period 1 + Period 2 groups** combine the participants who took Placebo with those who were taking AIN457 during Period 1. These are groups for participants who took AIN457 at any point in the study.

	Period 1 groups			Period 1 + Period 2 groups	
Participants who:	**AIN457 given every 2 weeks** 181 participants	**AIN457 given every 4 weeks** 180 participants	**Placebo** 180 participants	***Any* AIN457 given every 2 weeks** 266 participants	***Any* AIN457 given every 4 weeks** 267 participants
Had at least 1 adverse event	154 of 181 **(85%)**	154 of 180 **(86%)**	120 of 180 **(67%)**	220 of 266 **(83%)**	227 of 267 **(85%)**
Had at least 1 serious adverse event	13 of 181 **(7%)**	9 of 180 **(5%)**	6 of 180 **(3%)**	18 of 266 **(7%)**	19 of 267 **(7%)**
Stopped treatment due to an adverse event	10 of 181 **(6%)**	5 of 180 **(3%)**	1 of 180 **(1%)**	11 of 266 **(4%)**	7 of 267 **(3%)**
Died during the trial	0 of 181 **(0%)**	0 of 180 **(0%)**	0 of 180 **(0%)**	0 of 266 **(0%)**	0 of 267 **(0%)**

What serious adverse events did the participants have?

A total of 37 participants who received at least 1 dose of AIN457 had serious adverse events across Periods 1 and 2.

The table below shows the most common serious adverse events that happened in 2 or more participants.

	Period 1 groups			Period 1 + Period 2 groups	
	AIN457 given every 2 weeks 181 participants	**AIN457 given every 4 weeks** 180 participants	**Placebo** 180 participants	***Any* AIN457 given every 2 weeks** 266 participants	***Any* AIN457 given every 4 weeks** 267 participants
Hidradenitis that got worse Hidradenitis	3 of 181 **(2%)**	3 of 180 **(2%)**	2 of 180 **(1%)**	4 of 266 **(2%)**	4 of 267 **(2%)**
Sweat gland infection	1 of 181 **(1%)**	3 of 180 **(2%)**	0 of 180 **(0%)**	1 of 266 **(Under 1%)**	3 of 267 **(1%)**
Inflammation of the appendix Appendicitis	0 of 181 **(0%)**	1 of 180 **(1%)**	0 of 180 **(0%)**	1 of 266 **(Under 1%)**	1 of 267 **(Under 1%)**
COVID-19	1 of 181 **(1%)**	0 of 180 **(0%)**	0 of 180 **(0%)**	1 of 266 **(Under 1%)**	1 of 267 **(Under 1%)**
Deep bacterial infection of the skin Cellulitis	1 of 181 **(1%)**	1 of 180 **(1%)**	0 of 180 **(0%)**	1 of 266 **(Under 1%)**	1 of 267 **(Under 1%)**
Infection of the lungs Pneumonia	0 of 181 **(0%)**	0 of 180 **(0%)**	0 of 180 **(0%)**	0 of 266 **(0%)**	2 of 267 **(1%)**

What other adverse events did the participants have?

A total of 367 participants who received at least one dose of AIN457 had other adverse events across Periods 1 and 2.

The table below shows the other adverse events that happened in at least 5% participants of all participants. It includes participants whose HS got worse and was not considered serious.

	Period 1 groups			Period 1 + Period 2 groups	
	AIN457 given every 2 weeks 181 participants	**AIN457 given every 4 weeks** 180 participants	**Placebo** 180 participants	***Any* AIN457 given every 2 weeks** 266 participants	***Any* AIN457 given every 4 weeks** 267 participants
Headache	33 of 181 **(18%)**	32 of 180 **(18%)**	14 of 180 **(8%)**	39 of 266 **(15%)**	46 of 267 **(17%)**
Inflammation of the nose and throat Nasopharyngitis	32 of 181 **(18%)**	24 of 180 **(13%)**	13 of 180 **(7%)**	40 of 266 **(15%)**	29 of 267 **(11%)**
Hidradenitis that got worse Hidradenitis	16 of 181 **(9%)**	17 of 180 **(9%)**	23 of 180 **(13%)**	28 of 266 **(11%)**	26 of 267 **(10%)**
Diarrhea	11 of 181 **(6%)**	16 of 180 **(9%)**	9 of 180 **(5%)**	12 of 266 **(5%)**	24 of 267 **(9%)**
Fever Pyrexia	13 of 181 **(7%)**	8 of 180 **(4%)**	2 of 180 **(1%)**	16 of 266 **(6%)**	12 of 267 **(4%)**
Infection of the nose and throat Upper respiratory tract infection	9 of 181 **(5%)**	13 of 180 **(7%)**	4 of 180 **(2%)**	12 of 266 **(5%)**	17 of 267 **(6%)**

What was learned from this trial?

This trial helped researchers learn about the effects of AIN457, or secukinumab, in people with moderate to severe HS.

The researchers concluded that:

- A higher percentage of participants given **AIN457 300 mg every 2 weeks** or **every 4 weeks** had their HS symptoms reduced than those who were given placebo.
- For treatment with **AIN457 300 mg given every 2 weeks**, researchers determined that the difference compared to placebo was not due to chance.
- For treatment with **AIN457 300 mg given every 4 weeks**, researchers could not rule out that the difference was due to chance.
- Treatment with AIN457 was generally safe and no new unexpected safety concerns were found.

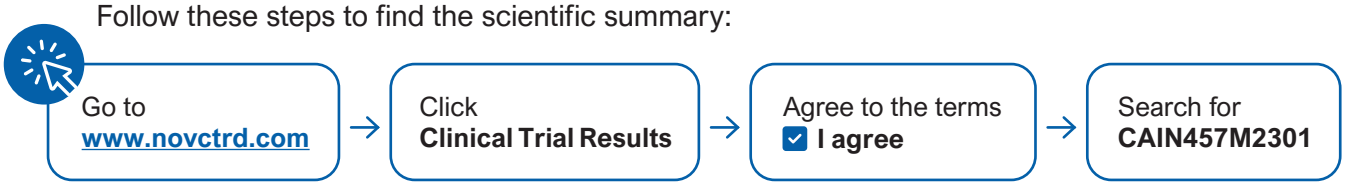
The results of this trial were submitted to health authorities in the European Union. In response, AIN457 given every 2 or 4 weeks received approval in the EU for the treatment of moderate to severe HS in adults.

Participants who completed treatment in this trial were offered to continue treatment in an extension trial, CAIN457M2301E1. Researchers are studying the long-term treatment of AIN457 for moderate to severe HS. At the time this summary was written, the extension trial is still ongoing.

Where can I learn more about this trial?

More information about the results and adverse events in this trial can be found in the scientific summary of the results available on the Novartis Clinical Trial Results website, **www.novctrd.com**.

Follow these steps to find the scientific summary:



For more information about this trial go to any of the following websites:

- **clinicaltrials.gov** – search using the number **NCT03713619**
- **clinicaltrialsregister.eu/ctr-search/search** – search using the number **2018-002063-26**

If more trials are planned, they will appear on the public websites above.
When there, search for AIN457, secukinumab, or Hidradenitis suppurativa.

Full clinical trial title: A Randomized, Double-Blind, Multi-Center Study Assessing Short (16 Weeks) and Long-Term Efficacy (Up to 1 Year), Safety, and Tolerability of 2 Subcutaneous Secukinumab Dose Regimens in Adult Patients With Moderate to Severe Hidradenitis Suppurativa (SUNSHINE)

NOVARTIS

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1-888-669-6682 (US); +41-61-324 1111 (EU)

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