Clinical Trial Results Summary

A clinical trial to learn more about the effects of AIN457 in children and adolescents with moderate to severe chronic plaque psoriasis

Thank you!

Thank you to the children, adolescents, and young adults who took part in the clinical trial for chronic plaque psoriasis. Every participant helped the researchers learn more about the trial drug **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 helps the participants understand their important role in medical research.

Trial information

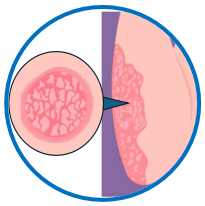
Trial number: CAIN457A2311
Drug studied: **AIN457**, also known as secukinumab
Sponsor: Novartis

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

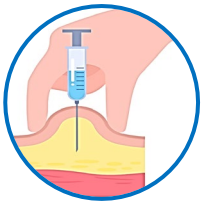
This summary only shows the results of a single clinical trial. Other clinical trials may have different findings.

What was the main purpose of this trial?

The purpose of this trial was to learn about the effects of 2 different dose levels of **AIN457** in children and adolescents with moderate to severe **chronic plaque psoriasis**.



Plaque psoriasis is a long-term skin condition that causes red, bumpy, and scaly patches called **plaques** on the skin. Psoriasis can appear anywhere on the body but mainly affects the elbows, knees, and scalp. Typical symptoms of plaque psoriasis include dry skin, rashes, itching, and burning sensation around the affected area.



AIN457, also called secukinumab**,** works by blocking certain inflammation-causing proteins in the body, which can help reduce symptoms related to inflammation including itch, pain, and swelling.

Trial drug
AIN457, also called secukinumab

Pronounced as
SEK-ue-KIN-ue-mab

When this study started, **AIN457** was already approved for the treatment of adults with moderate to severe plaque psoriasis. This study was done to seek approval for the use of **AIN457** in children and adolescents with moderate to severe plaque psoriasis.

In this trial, participants received a selected dose of **AIN457** as an injection under the skin. These doses were selected based on the participants' weight and the results of previous studies of **AIN457** in adults with psoriasis.

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The trial purpose was to answer these main questions:

- After 12 weeks of treatment with **AIN457**, how many participants had:
  - at least 75% improvement in their plaque psoriasis and
  - clear or almost clear skin based on the study doctor's assessment
- What adverse events did the participants have during this trial?

  An **adverse event** is any sign or symptom that the participants have during a trial.

How long was this trial?

The trial began in August 2018 and ended in September 2023. An individual participant could be in the trial for about 4 years after starting the trial treatment.

The trial ended as planned. When the trial ended, the researchers collected information from participants and created a report of the trial results. This summary is based on that report.

Who was in this trial?

84 participants with plaque psoriasis received treatment in this trial. Participants' ages ranged from 6 to less than 18 years. Their average age was 13 years.

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

Age group

- 33 — 6 to less than 12 years
- 51 — 12 to less than 18 years

Gender

- 39 — Boys
- 45 — Girls

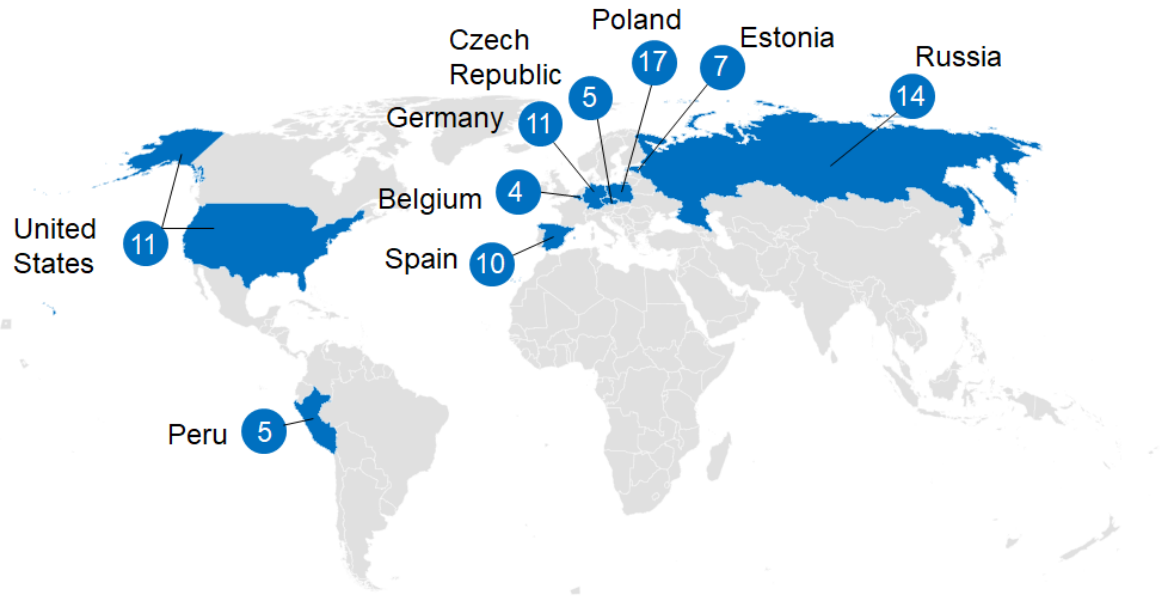
Race

- 5 — American Indian or Alaska Native
- 1 — Asian
- 1 — Black or African American
- 77 — White

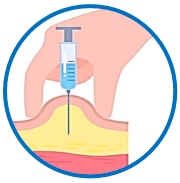
Participants could take part in this trial if they:

- were between 6 to less than 18 years of age
- had moderate to severe chronic plaque psoriasis for at least 3 months before starting the trial
- had psoriasis that did not respond to previous treatment or could not be effectively treated with creams and ointments or light therapy

84 participants from 9 countries were included in this trial and received treatment. The map below shows the number of participants who took part in each country.



What treatment did the participants receive?



The treatment in this trial was **AIN457,** given as an injection under the skin.

Participants received a **high-dose** or **low-dose AIN457** based on their body weight. This ensured that a similar amount of trial treatment was present in the participants' blood of the same group.

Participant weight	**High doses**	**Low doses**
Less than 25 kilograms (kg) (55 pounds)*	**AIN457 75 mg**	**AIN457 75 mg**
Between 25 and 49 kg (55 and 108 pounds)	**AIN457 150 mg**	**AIN457 75 mg**
50 kg (110 pounds) or more	**AIN457 300 mg**	**AIN457 150 mg**

*For this group high-dose and low-dose of **AIN457** were the same.

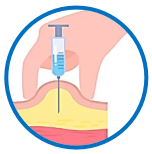
Everyone, including participants, parents, trial staff, and researchers knew what treatment the participants received.

What happened during this trial?

Before treatment — 1 month

Trial doctors checked the health and plaque psoriasis of the children and adolescents to ensure they could participate in this trial.

During treatment — 4 years of AIN457 treatment



Researchers used a computer program to randomly place participants into 2 different groups.

High-dose group
(42 participants)
Each participant took the selected high dose of **AIN457** according to their body weight

Low-dose group
(42 participants)
Each participant took the selected low dose of **AIN457** according to their body weight

All the participants received **AIN457** as injections under the skin once a week for the first month followed by once a month until the end of treatment.

Trial doctors closely monitored participants' plaque psoriasis throughout the trial.

After treatment — 4 months of follow-up after treatment

Participants returned to their trial site about 1 month after receiving the last dose of treatment. In the next 4 months, they visited the trial site 2 more times for overall health check-ups.

What was the main result of this trial?

After 12 weeks of treatment with AIN457, how many participants had:

- **at least 75% improvement in their plaque psoriasis and**
- **clear or almost clear skin based on the study doctor's assessment**

After 12 weeks of treatment in the **high-dose** group:

- 39 out of 42 (93%) participants showed at least 75% improvement in their plaque psoriasis
- 35 out of 42 (83%) participants had clear or almost clear skin

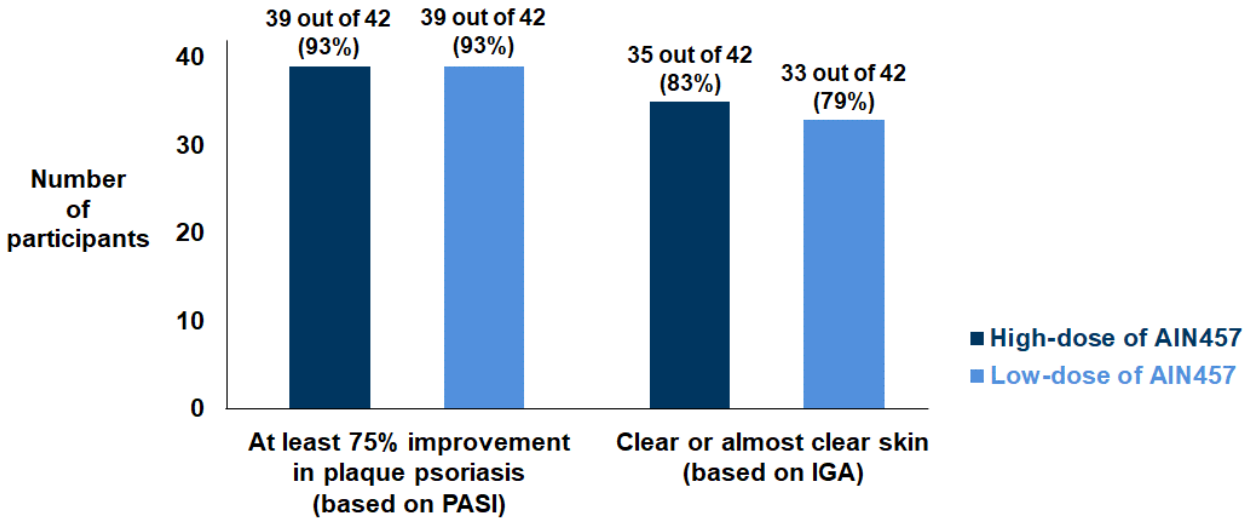
After 12 weeks of treatment in the **low-dose** group:

- 39 out of 42 (93%) participants showed at least 75% improvement in their plaque psoriasis
- 33 out of 42 (79%) participants had clear or almost clear skin

To answer this question, researchers used the following scoring methods:

- **Psoriasis Area Severity Index (PASI)** measures the severity of redness, scaling, and thickness of participants' plaque psoriasis, and how much of their body area is affected.
- **Investigator's Global Assessment (IGA)** measures psoriasis symptoms on a scale of 0 to 4, where 0 is no sign of psoriasis (clear skin) and 4 is severe thickening and bright to deep red skin.

Number of participants with at least 75% improvement in their plaque psoriasis and clear or almost clear skin based on the study doctor's assessment after 12 weeks of treatment



What were the other results of this trial?

How many participants had at least 90% improvement in their plaque psoriasis after 12 weeks of treatment with AIN457?

To answer this question, researchers assessed the severity of participants' plaque psoriasis using the PASI scoring method.

Researchers found that 32 out of 42 (76%) participants in the **high-dose** group and 29 out of 42 (69%) participants in the **low-dose** group had at least 90% improvement in their plaque psoriasis after 12 weeks of treatment.

More information about the results of this trial can be found on the scientific summary of results. See the last page on how to access the scientific summary of results.

What adverse events did the participants have?

Trial doctors keep track of all **adverse events** that happen in trials, even if they think the adverse events are not related to the trial treatments.

Many trials are needed to know if a drug or treatment causes an adverse event.

This section is a summary of the adverse events that happened from the start of treatment up to 20 weeks after receiving the last dose of **AIN457**.

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.

Most of the participants (68 out of 84) had adverse events. 6 participants had adverse events that were considered serious. 3 participants left the trial due to an adverse event. The researchers concluded there were no new safety concerns with the use of **AIN457** in this trial.

How many **participants** had adverse events?

Participants who:	High dose of AIN457 42 participants	Low dose of AIN457 42 participants
Had at least 1 serious adverse event	**2 of 42** 5%	**4 of 42** 10%
Had at least 1 other adverse event	**35 of 42** 83%	**33 of 42** 79%
Left the trial due to an adverse event	**2 of 42** 5%	**1 of 42** 2%

What serious adverse events did the **participants** have?

6 participants experienced a serious adverse event, but 7 serious adverse events are presented below. This is because 1 participant in the **low-dose** group of **AIN457** had 2 serious adverse events. The following serious adverse events were reported during the trial:

List of serious adverse events that occurred in each treatment group

High dose of AIN457 (1 participant each out of 42 participants)	Low dose of AIN457 (1 participant each out of 42 participants)
• **Inflammation of the appendix** (Appendicitis) • **Tonsillitis**	• **COVID-19 infection** • **Inflammation of the digestive tract** (Crohn's disease) • **Viral infection** (Infectious mononucleosis) • **Intentional self-injury** • **Broken leg bone** (Tibia fracture)

What other adverse events did the **participants** have?

The table below shows the other adverse events that were reported in more than 4 (10%) participants in either group.

	High dose of AIN457 42 participants	Low dose of AIN457 42 participants
COVID-19 infection	**9 of 42** 21%	**11 of 42** 26%
Common cold Nasopharyngitis	**7 of 42** 17%	**13 of 42** 31%
Acne	**2 of 42** 5%	**7 of 42** 17%
Viral infection of the nose and throat Viral upper respiratory tract infection	**7 of 42** 17%	**1 of 42** 2%
Fever Pyrexia	**1 of 42** 2%	**6 of 42** 14%
Infection of the nose and throat Upper respiratory tract infection	**6 of 42** 14%	**0**

Note: Participants could have more than 1 other adverse event during this trial.

What was learned from this trial?

Researchers learned about the effects of **AIN457** in children and adolescents with chronic plaque psoriasis.

Researchers concluded that:

- both **high dose** and **low dose** of **AIN457** showed improvement in participants' skin condition as assessed by different scoring methods.
- there were no new safety concerns with the use of **AIN457** in participants.

Based on the results of this study, the **low dose** of **AIN457** was the recommended dose for the initial treatment of chronic plaque psoriasis in children and adolescents.

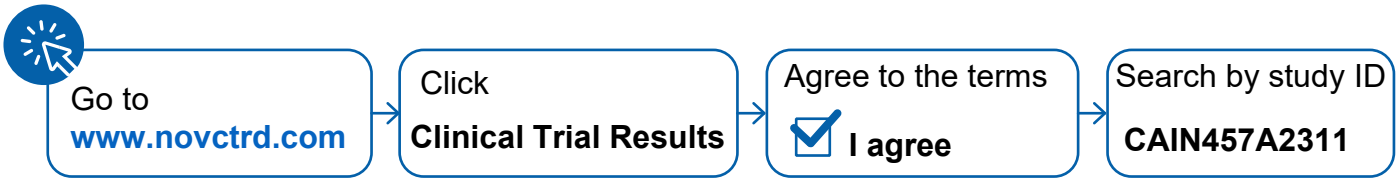
When this study started, **AIN457** was already approved for the treatment of adults with moderate to severe plaque psoriasis. The results of this study were used to obtain approval for the use of **AIN457** in children and adolescents with moderate to severe chronic plaque psoriasis.

Currently, there are no other trials planned with **AIN457** for moderate to severe chronic plaque psoriasis.

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 these websites:

- clinicaltrials.gov – search using the number **NCT03668613**
- clinicaltrialsregister.eu/ctr-search/search - search using the number **2017-004515-39**

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

Full clinical trial title: A randomized, open-label, multicenter trial to assess the efficacy of subcutaneous secukinumab after twelve weeks of treatment, and to assess the long-term safety, tolerability, and efficacy in subjects from 6 to less than 18 years of age with moderate to severe chronic plaque psoriasis

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