NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn about the long-term effects of AIN457 in children and adolescents with Juvenile Psoriatic Arthritis and Enthesitis Related Arthritis

Thank you!

Thank you to the participants who took part in the clinical trial for **juvenile psoriatic arthritis (JPsA) and enthesitis related arthritis (ERA)**, which are 2 types of **Juvenile Idiopathic Arthritis (JIA)**. 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 helps the participants understand their important role in medical research.

Trial information

Trial number: CAIN457F2304E1

Novartis 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 results.

What was the main purpose of this trial?

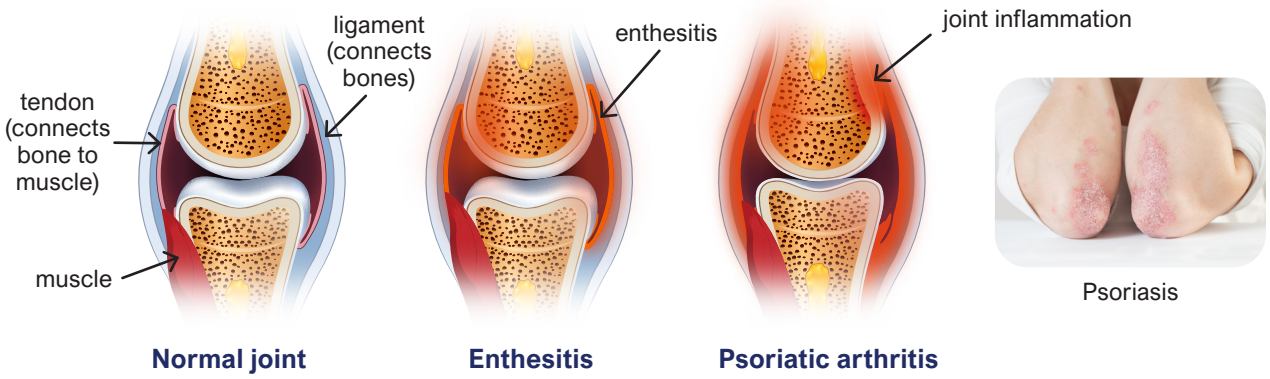
The main purpose of this trial was to learn about the long-term effects of **AIN457** in children and adolescents with juvenile idiopathic arthritis (JIA). This trial focused on 2 types of JIA: **juvenile psoriatic arthritis (JPsA) and enthesitis related arthritis (ERA)**.

Arthritis is a condition that causes pain and swelling in the joints. JIA is a type of arthritis that develops in children who are 16 years old or younger. It is an autoimmune disorder. This means the immune system, which normally protects the body, mistakenly attacks healthy tissues. This can lead to pain, inflammation, and stiffness in the joints. Without treatment, JIA may damage the joints, eyes, or other organs.

There are different types of JIA. In this trial, researchers studied:

Juvenile Psoriatic Arthritis (JPsA): JPsA usually affects the wrists, fingers, nails, and toes. It often occurs in children who have psoriasis or have a family history of **psoriasis**. Psoriasis is a skin condition that causes red, scaly, and itchy patches, known as plaques. These skin symptoms may appear before or after joint symptoms develop.

Enthesitis-Related Arthritis (ERA): ERA involves both arthritis and enthesitis. Enthesitis is inflammation in the areas where ligaments and tendons attach to bones. Ligaments connect bones to other bones. Tendons connect muscles to bones. ERA often affects the hips, knees, and feet.



The trial drug **AIN457** is a type of antibody that blocks a protein called **interleukin- 17A (IL-17A)**, which causes inflammation.

Antibodies are made by our immune system (the body's natural defense) to fight off infections or anything that is harmful to the body.

Drug
secukinumab

Pronounced as
se-koo-KI-noo-mab

AIN457, also known as **secukinumab**, is approved in many countries including the European Union and the United States for treating **JPsA** and **ERA.**

A previous trial, CAIN457F2304, studied **AIN457** in participants with **JPsA** and **ERA**. This trial is an extension trial to learn about its long-term effects in the same participants.

The trial's purpose was to answer these main questions:

- How many participants had an improvement in their JPsA and ERA symptoms over time?
- What medical problems, also called adverse events, happened during this trial?
  - ↳ An **adverse event** is any sign or symptom that participants have during a trial. Adverse events **may** or **may not** be caused by treatments in the trial.

How long was this trial?

The trial began in June 2019 and ended in November 2024. The treatment duration for this extension trial was up to 4 years.

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

Who was in this trial?

55 participants with **JIA** took part in this trial, and **54 participants** received treatment. This included 19 participants with **JPsA** and 35 participants with **ERA**.

Participants were between 2 and 17 years old when they joined the previous trial. Their average age was 13 years.

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

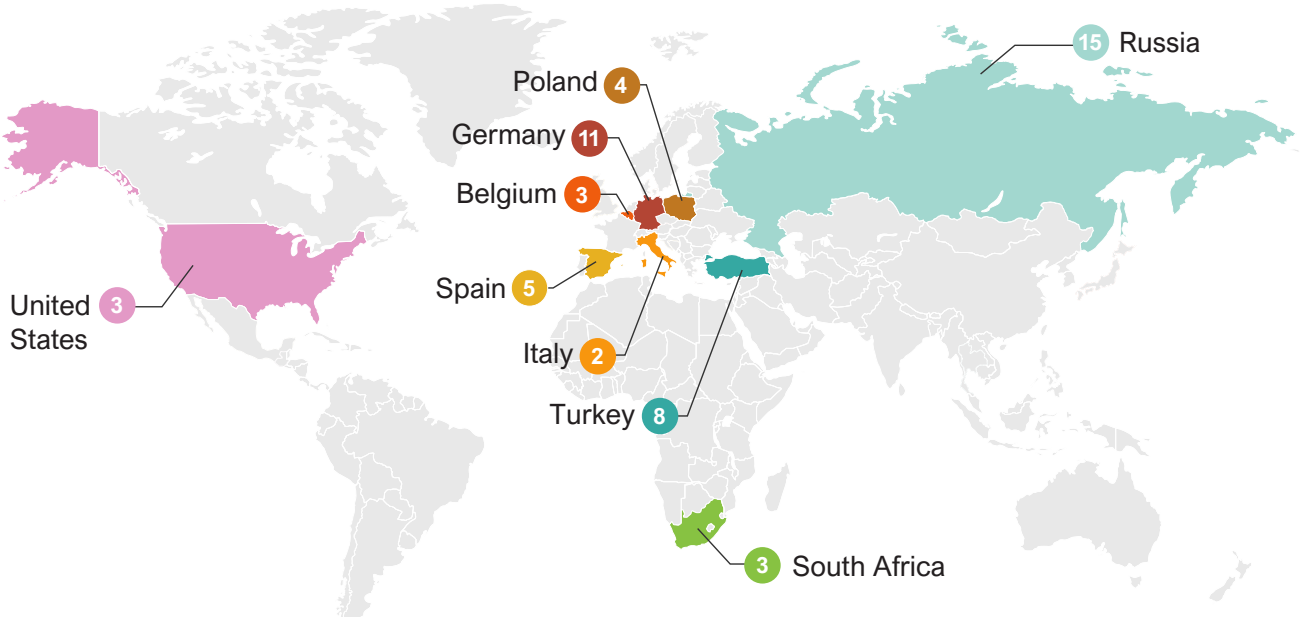
Gender

36 Boys	18 Girls

Race

52 White	2 Other

54 participants from **9 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 completed the entire treatment period of the previous trial, CAIN457F2304.
- **AIN457** treatment was providing a benefit in the opinion of the trial doctor.

What treatments did the participants receive?

The treatment in this trial was:

AIN457: 75, 150, or 300 milligrams (mg), given as an injection under the skin, once every 4 weeks.

Participants started this extension trial on either 75 mg or 150 mg of **AIN457**, the same dose they had in the previous trial. Per the trial doctor's decision, participants could have their doses increased to 150 mg or 300 mg if their symptoms were not controlled.

The participants, researchers, and trial staff knew what treatment the participants were receiving. The treatment dose was same as in the last visit of the previous trial. All participants received **AIN457**.

What happened during this trial?

Before the extension trial

All participants joined this trial after they completed the previous trial (CAIN457F2304), and had their health checked to make sure they could be in this trial.

During treatment

About 4 years

A total of 54 participants who received **AIN457** for 2 years in the previous trial continued to receive **AIN457** in this extension trial.

Participants were divided into 2 groups based on the **AIN457** dose they received in the previous trial.

AIN457, 75 mg
19 participants

AIN457, 150 mg
35 participants

Based on the trial doctor's decision, 16 participants had their **AIN457** dose increased to 300 mg. This could happen as early as the 2nd dose in this trial.

During the trial, participants were regularly checked for their overall health and for symptoms of JPsA and ERA.

After treatment

Up to 3 months after the last dose

Participants had a safety follow-up visit 3 months after their last dose of **AIN457**.

Trial staff checked the participants' general health throughout the trial.

What were the main results of this trial?

How many participants had an improvement in their JPsA and ERA symptoms over time?

Researchers found that nearly all participants had an improvement in their **JPsA** and **ERA** symptoms.

Researchers wanted to see if participants had an improvement in their JPsA and ERA symptoms. To measure this, they used a tool called the **JIA American College of Rheumatology (ACR).**

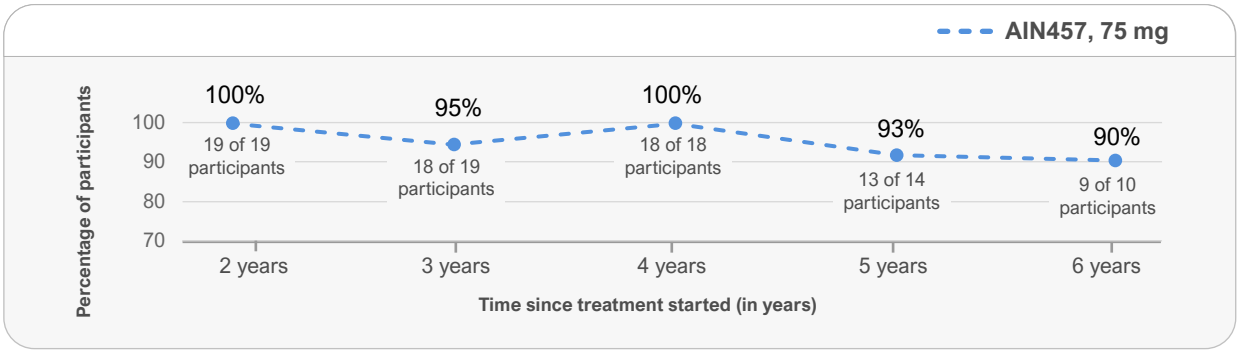
The JIA ACR tool looked at several things, including:

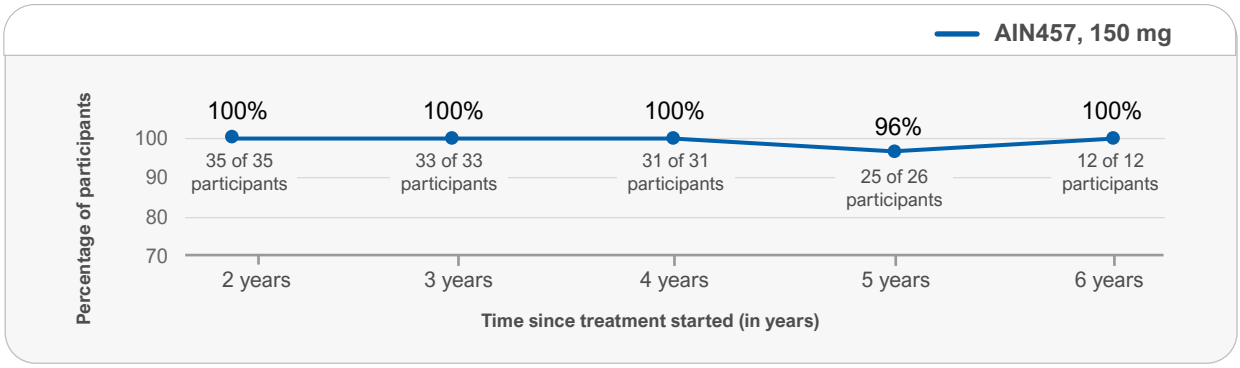
- How well participants could move and perform daily activities.
- The number of joints affected by arthritis or with limited movement.
- A doctor's assessment of the participants' symptoms.
- Participants' own rating of how they were feeling overall.
- Blood tests to check for signs of inflammation.

This graph below shows the percentage of participants whose symptoms improved by at least 30% over time, based on the JIA ACR tool compared to when they started the trial.

Results are shown for the extension trial only, where participants had already been receiving **AIN457** for 2 years as part of the previous trial before joining.

Participants with improvement in JIA ACR 30 (JPsA and ERA symptoms) over time





Fewer participants stayed in the trial over time, mainly because **AIN457** became available in several countries. They chose to leave the trial and receive the treatment through their usual healthcare providers.

What medical problems, also called adverse events, happened during this trial?

Trial doctors keep track of all **medical problems,** also called **adverse events,** that happen in trials. They track adverse events 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 the extension trial up to 3 months after the last dose.

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.

A total of **46 out of 54 (85%)** participants had adverse events.

- 4 participants had adverse events that were considered serious.
- 1 participant left the trial due to an adverse event.
- None of the participants died.

There were no new, unexpected safety concerns with **AIN457**.

How many participants had adverse events?

The table below shows how many participants had adverse events during this extension trial.

Participants who increased their dose from 75 mg to 150 mg or from 150 mg to 300 mg were counted in the group they were in at the time the adverse event happened.

Summary of adverse events

	AIN457, 75 mg 19 participants	AIN457, 150 mg 43 participants	AIN457, 300 mg 16 participants
Had any adverse event, including **serious and other**	15 of 19 (79%)	34 of 43 (79%)	11 of 16 (69%)
Had at least **1 serious adverse event**	0 of 19 (0%)	4 of 43 (9%)	0 of 16 (0%)
Left the trial due to an adverse event	0 of 19 (0%)	1 of 43 (2%)	0 of 16 (0%)

What serious adverse events did the participants have?

The table below shows the serious adverse events that happened during the trial. In total, 4 participants had serious adverse events. However, some participants had multiple events.

Serious adverse events

	AIN457, 75 mg 19 participants	AIN457, 150 mg 43 participants	AIN457, 300 mg 16 participants
Sudden inflammation of the sinuses Acute sinusitis	0 of 19 (0%)	1 of 43 (2%)	0 of 16 (0%)
Bleeding in the brain Cerebral hemorrhage	0 of 19 (0%)	1 of 43 (2%)	0 of 16 (0%)
A temporary head injury Concussion	0 of 19 (0%)	1 of 43 (2%)	0 of 16 (0%)
An inflammatory disease affecting the gut Crohn's disease	0 of 19 (0%)	1 of 43 (2%)	0 of 16 (0%)
Head injury	0 of 19 (0%)	1 of 43 (2%)	0 of 16 (0%)
Kidney stones Nephrolithiasis	0 of 19 (0%)	1 of 43 (2%)	0 of 16 (0%)
Bleeding in the space that surrounds the brain Subarachnoid hemorrhage	0 of 19 (0%)	1 of 43 (2%)	0 of 16 (0%)
Build-up of blood on the surface of the brain Subdural hematoma	0 of 19 (0%)	1 of 43 (2%)	0 of 16 (0%)
Bleeding in the tube that leads from the bladder to the outside Urethral hemorrhage	0 of 19 (0%)	1 of 43 (2%)	0 of 16 (0%)

What other (not including serious) adverse events did the participants have?

The table below shows the most common other adverse events that happened during the trial.

Other adverse events	AIN457, 75 mg 19 participants	AIN457, 150 mg 43 participants	AIN457, 300 mg 16 participants
COVID-19	1 of 19 (5%)	9 of 43 (21%)	3 of 16 (19%)
Inflammation of the nose and throat Nasopharyngitis	2 of 19 (11%)	8 of 43 (19%)	4 of 16 (25%)
Joint pain Arthralgia	4 of 19 (21%)	7 of 43 (16%)	3 of 16 (19%)
Pain in arm or leg Pain in extremity	1 of 19 (5%)	8 of 43 (19%)	0 of 16 (0%)
Diarrhea	1 of 19 (5%)	5 of 43 (12%)	1 of 16 (6%)
Infection of the nose, sinuses, and the upper throat Upper respiratory tract infection	2 of 19 (11%)	5 of 43 (12%)	0 of 16 (0%)
Stomach pain Abdominal pain upper	3 of 19 (16%)	4 of 43 (9%)	0 of 16 (0%)
Back pain	2 of 19 (11%)	3 of 43 (7%)	0 of 16 (0%)
Inflammation of the sinuses Sinusitis	2 of 19 (11%)	2 of 43 (5%)	1 of 16 (6%)

What was learned from this trial?

This trial helped researchers learn about the effects of **AIN457** in people with **juvenile psoriatic arthritis (JPsA)** and **enthesitis related arthritis (ERA)**.

The researchers concluded that:

- Nearly all the participants who had an improvement in symptoms in the previous trial continued to respond to treatment with **AIN457** in this extension trial.
- There were no new, unexpected safety concerns with **AIN457**.

When this summary was written, the sponsor had no plans for future trials of **AIN457** in people with **JPsA** and **ERA**.

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:

Go to **www.novctrd.com** → Click **Clinical Trial Results** → Accept the terms ☑ **I accept** → Search for **CAIN457F2304E1**

For more information about this trial extension, go to any of these websites:

- clinicaltrials.gov – search using the number **NCT03769168**
- clinicaltrialsregister.eu – search using the number **2018-002521-30**

Other studies with **AIN457** appear on the public websites above. When there, search for **AIN457** or **secukinumab**.

You may also find information about the previous trial by searching for CAIN457F2304.

Full clinical trial title: An Extension Study of Subcutaneous Secukinumab To Evaluate The Long-Term Efficacy, Safety And Tolerability Up To 4 Years In Patients With Juvenile Idiopathic Arthritis Subtypes Of Juvenile Psoriatic Arthritis And Enthesitis

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