NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about the effects of AIN457 in Chinese adults with active psoriatic arthritis

Thank you!

Thank you to the participants who took part in the clinical trial for active **psoriatic arthritis**. 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: CAIN457F2367

Drug studied: **AIN457** also known as **secukinumab**

Sponsor: Novartis

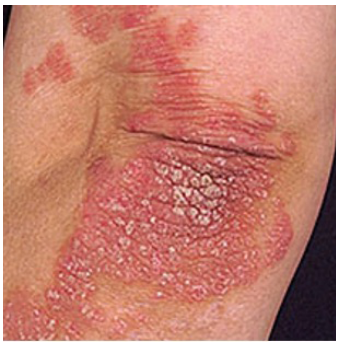
If you were a participant and have any questions about the results, please talk to the doctor or staff at the trial site.

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 **AIN457** in Chinese adults with active **psoriatic arthritis** (**PsA**). To find this out, researchers compared the effects of **AIN457** to a **placebo**.

PsA is an illness that can affect the skin and joints. It results in pain, tenderness, and limited function of joints. Joints are stiff, inflamed, with redness and warmth. It also results in patches of thick, red, raised skin covered with scales on any part of the body. Scales are a silvery-white buildup of dead skin cells. These symptoms can become aggressive at times if not managed carefully. Researchers believe that in **PsA** the immune system mistakenly attacks its own tissues.



Source: mayo clinic

PsA is treated with painkillers and drugs that work by blocking proteins that cause inflammation.

AIN457 reduces the activity of a protein called Interleukin-17A that is responsible for inflammation and helps relieve **PsA** symptoms.

AIN457 is approved for the treatment of active **PsA** in adults in the United States, the European Union and Japan. This trial was done with Chinese participants to support the approval of **AIN457** to treat adults with active **PsA** in China.

A **placebo** looks like the trial drug but does not have any trial drug in it. Using a **placebo** helps researchers better understand the effect of a trial drug.

Trial drug
Secukinumab

Pronounced as
Sek-cu-KIN-umab

The trial purpose was to answer these main questions:

- How many participants who received **AIN457 150 mg** had improvement in their **PsA** symptoms after 16 weeks of treatment compared to those who received **placebo**?
- What adverse events did the participants have during this trial?
  - ↳ An **adverse event** is any sign or symptom that participants have during a trial.

How long was this trial?

The trial began in June 2021 and ended in March 2023. It was planned for the participants to be in the trial for about 1 year and 2 months after receiving the trial treatment.

Who was in this trial?

41 participants from China with active **PsA** received treatment in this trial. Participants' ages ranged from 21 to 64 years. Their average age was 44 years. The number of participants by gender is shown below.

Gender

23 Men	18 Women

The participants could take part in this trial if they:

- were Chinese and aged 18 years or older,
- were diagnosed with moderate to severe **PsA** with symptoms for at least 6 months,
- were not treated earlier with **AIN457** or medicines which work in a similar way, and
- were not taking any medicines or had a medical condition that could interfere with the trial results, as verified by the trial doctor.

What treatments did the participants receive?

The treatments in this trial were:

AIN457, also known as **secukinumab**, was given at a dose of 150 milligrams (mg) or 300 mg as an injection under the skin. It was given every week in the first month from Day 1 and then every 4 weeks.

Placebo looks like the trial drug but does not have any trial drug in it. Using a **placebo** helps researchers better understand the effect of a trial drug.

Participants were allowed to take some medicines called rescue medications after 16 weeks of treatment with the permission of the trial doctor. Rescue medications are given to relieve **PsA** symptoms immediately if participants do not get relief from their **PsA** symptoms during trial treatment.

Researchers randomly assigned participants to treatment groups using a computer system.

In this trial, none of the participants, trial doctors, or trial staff knew what treatment the participants were receiving. Some trials are done this way because knowing what treatment each participant is getting can affect the result of the trial. Doing a trial this way helps to make sure that the results are looked at with fairness towards all treatments.

What happened during this trial?

Before treatment — About 2 Months

Trial doctors checked the participants' health and active **PsA** to make sure they could be in this clinical trial.

During treatment — 1 Year

The trial had 2 treatment periods:

Period 1: From Day 1 (first dose) to Week 16

41 participants were randomly assigned to one of the two groups:

AIN457 150 mg (20 participants)	**Placebo** (21 participants)

Period 2: From Week 16 to Week 52

At Week 16, all 41 participants from both groups, were randomly re-assigned to receive **AIN457**.

AIN457 150 mg (20 participants)	**AIN457 300 mg** (21 participants)

The treatment was given as an injection every week from Day 1 in the first month and then every 4 weeks until Week 48.

By the end of both treatment periods,

- 21 out of 41 participants had received **placebo**,
- 30 out of 41 participants had received **AIN457 150 mg** and
- 21 out of 41 participants had received **AIN457 300 mg**.

Trial doctors checked the participants' health throughout the trial.

After treatment — 2 Months

Participants returned to their trial site for two follow-up visits after their last dose of treatment to check their overall health.

What are the main results of this trial?

How many participants who received AIN457 150 mg had improvement* in their PsA symptoms after 16 weeks of treatment compared to those who received placebo?

*Improvement means at least a 20% decrease in **PsA** symptoms.

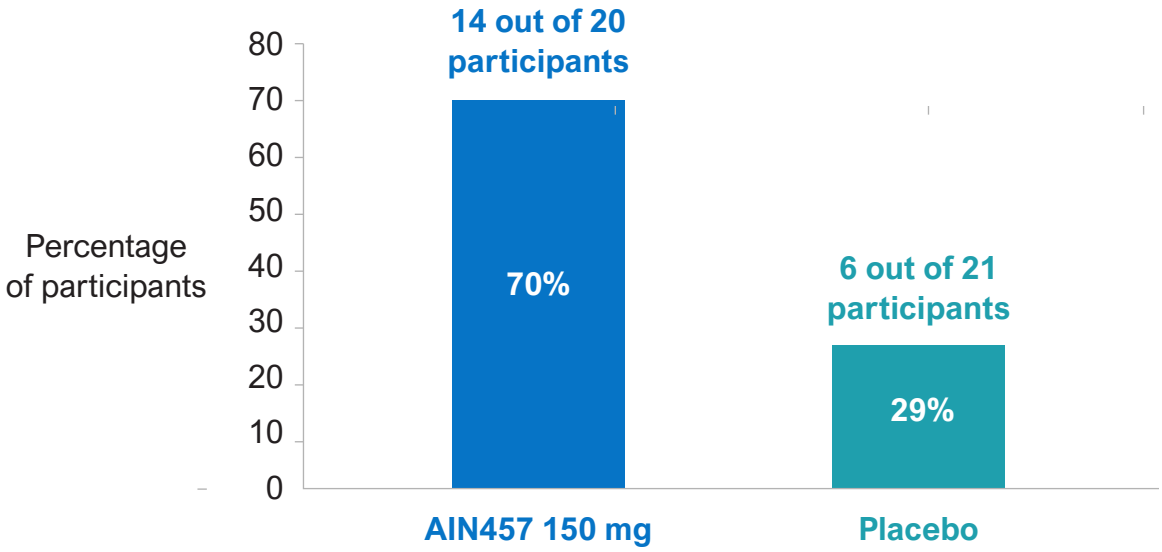
14 out of 20 participants (70%) who received **AIN457 150 mg** had improvement in their **PsA** symptoms compared to 6 out of 21 participants (29%) who received **placebo**.

To measure the improvement of **PsA** symptoms, researchers used an assessment system called the **American College of Rheumatology (ACR)** response.

This is based on observations by both the participant and the researcher. The observations included: **PsA** symptoms, pain, participant's ability to do their daily activities, blood tests to check for signs of swelling, and the number of tender and swollen joints.

Researchers then compared the number of participants in each treatment group who had improvement in their **PsA** symptoms.

Participants with improvement in their **PsA** symptoms



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 2 months after the end of the trial treatment.

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.

By the end of the treatment, up to Week 48, all 41 participants had received **AIN457**, in either 150 mg or 300 mg doses. As **placebo** was only given during period 1 up to Week 16, only 21 of the 41 participants received **placebo**. These 21 participants later received **AIN457 150 mg** or **AIN457 300 mg** during period 2.

90% (37 of 41) of the participants who received any **AIN457** and 76% (16 of 21) of the participants who received **placebo** had adverse events. 2% (1 of 41) participants had adverse events that were considered serious. No participant died or left the trial due to an adverse event.

The researchers concluded that there were no new safety concerns for **AIN457** for this trial.

How many participants had adverse events?

Participants who:	AIN457 150 mg 30 participants	AIN457 300 mg 21 participants	Placebo 21 participants
Had at least 1 serious adverse event	0 of 30 0%	1 of 21 5%	0 of 21 0%
Had at least 1 other adverse event	27 of 30 90%	16 of 21 76%	16 of 21 76%

No participant died or left the trial due to an adverse event.

What serious adverse events did the participants have?

1 participant who received **AIN457 300 mg** had serious adverse events.
No participant died.

The participant reported **clouding of the eye** (cataract) and **formation of an abnormal membrane on the retina** (epiretinal membrane). Retina is the part at the back of the eye which helps to see things.

What other adverse events did the participants have?

27 participants who received **AIN457 150 mg**, 16 participants who received **AIN457 300 mg** and 16 participants who received **placebo** had other adverse events.

The table below shows the other adverse events that happened in **10% or more** participants in any treatment group.

	AIN457 150 mg 30 participants	AIN457 300 mg 21 participants	Placebo 21 participants
Abnormal liver function Hepatic function abnormal	3 of 30 10%	2 of 21 10%	0 of 21 0%
COVID-19	4 of 30 13%	5 of 21 24%	0 of 21 0%
High levels of bad cholesterol Hypercholesterolaemia	5 of 30 17%	0 of 21 0%	0 of 21 0%
High blood pressure Hypertension	4 of 30 13%	0 of 21 0%	1 of 21 5%
High levels of fat in the blood Hyperlipidaemia	6 of 30 20%	3 of 21 14%	8 of 21 38%
High uric acid levels in the blood Hyperuricaemia	5 of 30 17%	4 of 21 19%	2 of 21 10%
Suspected COVID-19	3 of 30 10%	2 of 21 10%	0 of 21 0%
Weight increased	3 of 30 10%	0 of 21 0%	1 of 21 5%

What was learned from this trial?

Researchers learned about the effects of **AIN457** in Chinese adults with active **PsA**.

- Participants who received **AIN457 150 mg** had more improvement in their active **PsA** symptoms compared to those who received **placebo**.
- Researchers found no new safety concerns for **AIN457**.

At the time of this report, some participants from this trial were included in an ongoing trial with **AIN457**.

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** → Agree to the terms ☑ **I agree** → Search for **CAIN457F2367**

For more information about this trial, go to this website:

- **clinicaltrials.gov** – search using the number **NCT04711902**

Other trials will appear on the public website above. When there, search for **AIN457** and/or secukinumab.

Full clinical trial title: A phase III randomized, double-blind, placebo controlled, multicenter, bridging study of subcutaneous secukinumab, to demonstrate efficacy after sixteen weeks of treatment and to assess safety, tolerability and long-term efficacy follow-up to one year in Chinese subjects with active psoriatic arthritis

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