NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about the effects of secukinumab in Chinese adults with non-radiographic axial spondyloarthritis

Thank you!

Thank you to the participants who took part in the clinical trial for **non-radiographic axial spondyloarthritis**. Every participant helped to learn more about the trial drug **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: CAIN457I2301

Novartis drug studied: **secukinumab**, also called **AIN457**

Sponsor: Novartis

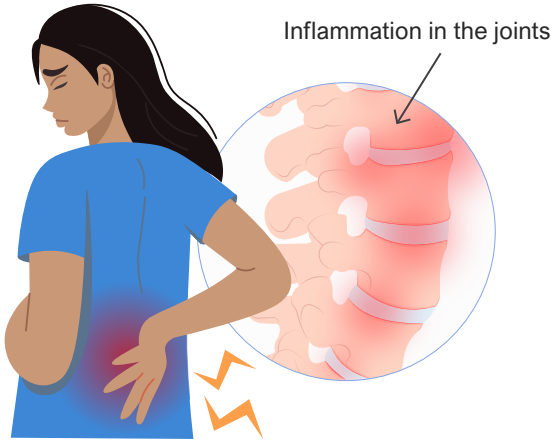
If you were a participant and have any questions about the results, please talk to the doctor or staff at the trial site.

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 **secukinumab** in Chinese adults with **non-radiographic axial spondyloarthritis**.

Axial spondyloarthritis is a type of arthritis that causes pain, stiffness, and swelling in the joints, especially in the spine and the lower part of the back. It is an auto-inflammatory disease. This means the immune system, which normally protects the body, has an abnormal response and leads to inflammation in the joints and surrounding area.



Non-radiographic axial spondyloarthritis

Axial spondyloarthritis is often detected using imaging tests, such as MRI or X-rays. It has two types:

- **Non-radiographic axial spondyloarthritis**: People may have back pain and other symptoms, but X-rays appear normal and do not show any clear signs of damage.
- **Ankylosing spondylitis (radiographic axial spondyloarthritis)**: X-rays show visible joint damage, such as changes in the bones or joints, often affecting the lower part of the back.

Treatment for **axial spondyloarthritis** focuses on controlling the symptoms, preventing further worsening of inflammation and permanent bone damage. **Tumor necrosis factor-alpha (TNF-α)** inhibitors are one type of treatment usually given to reduce inflammation and help manage symptoms. However, they may not work for everyone.

What are Monoclonal antibodies?

Antibodies are made by our immune system to fight off infections or anything that is harmful to our body. Monoclonal antibodies are a type of antibody that is made in a lab and are developed to target specific proteins in the body.

The trial drug, **secukinumab**, is a type of drug known as a monoclonal antibody created to block a protein called **interleukin-17A *(IL-17A)***, which causes inflammation. *IL-17A* is a protein that triggers cells in the immune system to help fight infection or repair injuries.

Secukinumab is approved in many countries, including the European Union and the United States, for treating **non-radiographic axial spondyloarthritis**. In China, **secukinumab** is approved for ankylosing spondylitis.

Trial drug

secukinumab also called **AIN457**

Pronounced as

se-koo-KI-noo-mab

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

- How many participants' spondyloarthritis symptoms improved after 16 weeks of treatment?
- 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 July 2021 and ended in February 2025. The trial was designed so that each participant would take part for up to 16 months. The participants started the trial on different dates.

At the end of this trial, Novartis created a report of the trial results. This summary is based on that report.

Who was in this trial?

137 participants from **China** with **non-radiographic axial spondyloarthritis** received treatment in this trial – 97 males and 40 females. Participants' ages ranged from 18 to 54 years. Their average age was 29 years.

All 137 participants were **Asian** by race.

The participants **could take part** in this trial if they:

- Were at least 18 years old.
- Had **non-radiographic axial spondyloarthritis** and their doctor had confirmed they did not have ankylosing spondylitis.
- Never received **secukinumab** or other drugs that block the IL-17 protein.

What treatments did the participants receive?

The treatments in this trial were:

Secukinumab: **150 or 300 milligrams (mg)**, given as injections under the skin. The 300 mg dose was given as 2 injections of 150 mg each.

Placebo: given as injections under the skin. A **placebo** looks like the trial drug but does not have any drug in it. Researchers use a **placebo** to better understand the effect of a trial drug.

Participants received treatment in 2 parts. **Part 1** treatment lasted up to 16 weeks. **Part 2** treatment was 36 weeks.

During **Part 1**, researchers used a computer to randomly assign participants equally to either the **secukinumab** group or the **placebo** group. The participants, researchers, and trial staff did not know whether the participants received **secukinumab** or **placebo**. Doing a trial this way helps to make sure that the results are looked at with fairness across all treatments.

During **Part 2**, all participants received **secukinumab** until the end of the treatment period. The participants and the trial staff knew that all participants received **secukinumab** treatment.

What happened during this trial?

Before treatment

Up to 10 weeks

The trial staff checked to make sure the participants could be in this trial.

During treatment

Up to 52 weeks

During **Part 1**, 137 participants were assigned to receive one of the treatments below.

Secukinumab	**Placebo**
68 participants	69 participants

Participants received their treatments once a week during Weeks 0, 1, 2, 3, and 4, and then every 4 weeks until Week 16. Two participants did not complete Part 1 of the trial and therefore did not continue into Part 2.

Part 2 began with 135 participants at Week 16 and lasted for an additional 32 weeks. All participants received **secukinumab** until the end of this treatment period. **Placebo** was no longer given.

Secukinumab
135 participants

At Week 24, 29 participants who did not respond to the 150 mg secukinumab treatment could receive 300 mg of **secukinumab** instead. Those who responded continued to receive 150 mg every 4 weeks until the end of the treatment period.

Trial staff checked participants' general health and for any medical problems at week 52, which was one month after their last dose.

After treatment

Up to 8 weeks

Participants had a follow-up visit at Week 60.

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

What were the main results of this trial?

How many participants who had not previously received TNF-α inhibitor treatment had their spondyloarthritis symptoms improve after 16 weeks of treatment?

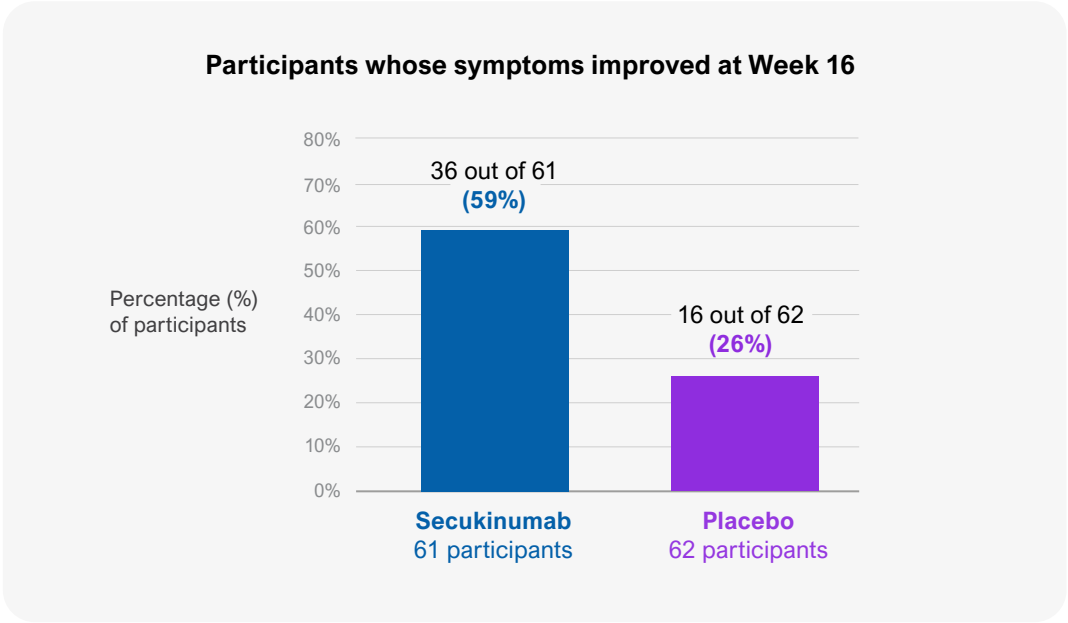
Researchers found that **59% of participants** who were given **secukinumab** and **26% of participants** who were given **placebo** and had not previously received TNF-α inhibitor treatment had an improvement in their symptoms after 16 weeks of treatment.

Researchers wanted to see if participants' spondyloarthritis symptoms improved after 16 weeks of treatment. To measure this, they checked if participants had an **Ankylosing Spondyloarthritis International Society (ASAS40) response**.

An **ASAS40** response means a participant had an improvement of at least 40% in their symptoms. This is based on several questionnaires that measure their level of pain, stiffness, and the ability to perform daily activities.

The graph below shows how many participants had an ASAS40 response at Week 16, compared with their symptoms measured at the start of the trial.

The results include only the participants who had not previously received **TNF-α inhibitor** treatment and had answered all of the required questionnaires.



What were the other results of this trial?

Overall, how many participants' spondyloarthritis symptoms improved after 16 weeks of treatment?

These overall results were reported for all participants who had or had not received TNF-α inhibitor treatment and took either **secukinumab** or **placebo** during this trial.

Researchers found that **60% of participants** who were given **secukinumab** and **25% of participants** who were given **placebo** had an improvement in their symptoms after 16 weeks of treatment.

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 do this even if they think the adverse events are not related to the trial treatments.

Researchers need results from many trials to decide if a drug or treatment causes an adverse event.

This section is a summary of the adverse events that happened from the day participants started the trial treatments until 1 month 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.

The researchers concluded there were no new or unexpected safety concerns for **secukinumab** in this trial.

What serious adverse events did the participants have?

7 participants had serious adverse events and no participants died.

The table below shows the serious adverse events that happened in 1 participant each.

The **Any secukinumab** group included all participants who received **secukinumab** at any time during the trial, in either **Part 1** or **Part 2**.

The **Placebo** group includes only the participants who had adverse events during **Part 1**, since all participants were taking **secukinumab** during **Part 2**.

	Any Secukinumab 135 participants	**Placebo** 69 participants
Inflammation and damage to the stomach lining Gastritis erosive	1 of 135 (1%)	0 of 69 (0%)
A tunnel that forms between the skin and the anus, often caused by infection Anal fistula	0 of 135 (0%)	1 of 69 (1%)
Infection under the fingernail or toenail Paronychia	1 of 135 (1%)	0 of 69 (0%)
Infection of the tonsils Tonsillitis	1 of 135 (1%)	0 of 69 (0%)
Rib fracture	1 of 135 (1%)	0 of 69 (0%)
A rare tumor in the rectum Neuroendocrine tumor of the rectum	1 of 135 (1%)	0 of 69 (0%)
Breast swelling caused by immune cells Plasma cell mastitis	1 of 135 (1%)	0 of 69 (0%)

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

The table below shows the most common other adverse events.

The **Any secukinumab** group included all participants who received **secukinumab** at any time during the trial, in either **Part 1** or **Part 2**.

The **Placebo** group includes only the participants who had adverse events during **Part 1**, since all participants were taking **secukinumab** during **Part 2**.

	Any Secukinumab 135 participants	**Placebo** 69 participants
Nose and throat infection Upper respiratory tract infection	49 of 135 (36%)	22 of 69 (32%)
High blood levels of uric acid Hyperuricaemia	28 of 135 (21%)	10 of 69 (14%)
COVID-19	27 of 135 (20%)	7 of 69 (10%)
High blood levels of fat Hyperlipidemia	23 of 135 (17%)	10 of 69 (14%)

What was learned from this trial?

Researchers learned about the effects of **secukinumab** in people with **non-radiographic axial spondyloarthritis**.

The researchers concluded that:

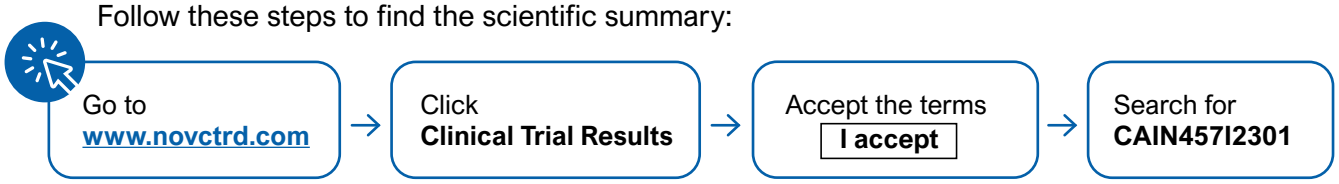
- Among the participants, a higher percentage of those who received **secukinumab** had an improvement in their symptoms compared to those who received **placebo**.
- There were no new or unexpected safety concerns for **secukinumab** in this trial.

When this summary was written, Novartis had an ongoing trial of **secukinumab** for people with **non-radiographic axial spondyloarthritis**.

Where can I learn more about this trial?

To learn more about the results and adverse events in this trial, read the scientific summary of the results. It is 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 this website:

clinicaltrials.gov – search using the number **NCT04732117**

Other trials of **secukinumab** may appear on the public websites above. When there, search for **secukinumab** or **AIN457**.

Full clinical trial title: A randomized, double-blind, placebo controlled, multicenter, phase III study of subcutaneous secukinumab to compare efficacy at 16 weeks with placebo and to assess safety and tolerability up to 52 weeks in Chinese participants with active non-radiographic axial spondyloarthritis.

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