NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn about the effects of secukinumab in people with rotator cuff tendinopathy

Thank you!

Thank you to the participants who took part in the clinical trial for **rotator cuff tendinopathy**. Every participant helped the researchers 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: CAIN457FDE05

Drug studied: **Secukinumab**, also known as **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.

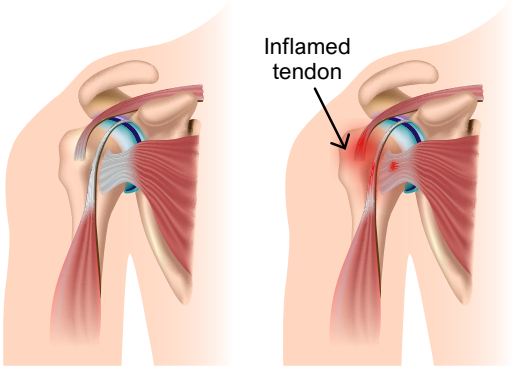
This summary only shows the results of a single clinical trial. Other clinical trials may have different results.

What was the main purpose of this trial?

The main purpose of this trial was to find out if **secukinumab** can help improve the signs and symptoms of moderate to severe **rotator cuff tendinopathy**.

The rotator cuff is a group of muscles and tendons that connect the upper arm bone to the shoulder blade. Tendons are tissues that join muscles to bones. **Rotator cuff tendinopathy** is a common condition where the tendons become inflamed or damaged. It is often caused by overuse or injury of the shoulder.

Common symptoms of **rotator cuff tendinopathy** include pain during activities, weakness, and difficulty using the shoulder normally.



Normal **Rotator cuff tendinopathy**

Current standard treatments include exercises with a physical therapist and medicines like anti-inflammatory drugs, steroids, and pain relievers. However, these treatments do not work for everyone, and long-term use of these medicines can cause unwanted side effects.

The trial drug, **secukinumab**, is a type of **antibody** that blocks a protein called **interleukin-17A (IL-17A)**, which causes inflammation. **Secukinumab** is approved in many countries, including the European Union and the United States, for treating other conditions such as arthritis.

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

IL-17A is a protein that triggers cells in the immune system to help fight infection or repair injuries.

In this trial, researchers wanted to learn about the effects of **secukinumab** when added to standard treatment in people with moderate to severe **rotator cuff tendinopathy**. To do this, they compared **secukinumab** with **placebo**. A placebo looks like the trial drug but does not have any drug in it. Using a **placebo** helps researchers better understand the effect of a trial drug.

Drug
secukinumab

Pronounced as
se-koo-KI-noo-mab

The main questions that researchers wanted to answer were:

- Did **secukinumab** help improve participants' **rotator cuff tendinopathy** symptoms?
- 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 December 2022 and ended in December 2024. The trial was designed so that each participant would take part for up to 32 weeks.

The trial ended earlier than planned, and as a result, a smaller number of participants took part than originally planned.

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

Who was in this trial?

62 participants from Germany with **rotator cuff tendinopathy** received treatment in this trial. Participants' ages ranged from 31 to 65 years. Their average age was 52 years.

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

Sex

35 Female	27 Male

Race

60 Caucasian	1 Black	1 Asian

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

- Were between 18 and 65 years old.
- Had moderate to severe **rotator cuff tendinopathy**.
- Had either no tear in the tendon or a tear that went through less than half of the tendon.
- Had been experiencing symptoms for at least 6 weeks but not more than 6 months before starting treatment in this trial.
- Had tried standard treatments for at least 8 weeks without improvement anytime before joining the trial.

What treatments did the participants receive?

Researchers studied the following treatments:

Secukinumab: 300 milligrams (mg), given as injections under the skin.

Placebo: given as injections under the skin. A **placebo** looks like the trial drug but does not have any drug in it.

Researchers used a computer to randomly assign participants to receive either **secukinumab** or **placebo**.

All participants also received standard treatment for their condition as decided by their trial doctor. This included physical therapy and anti-inflammatory drugs.

The participants, researchers, and trial staff did not know what treatment the participants were receiving. Some trials are done this way because knowing what treatment the participants receive can affect the results of the trial. 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 8 weeks

First, the trial staff checked to make sure the participants could be in this trial. This could take up to 6 weeks.

Then, participants spent 2 weeks doing physical therapy and taking anti-inflammatory drugs at home. Their trial doctor adjusted their doses as needed. This was part of the participant's standard treatment.

Only participants who did not benefit from the standard treatment were allowed to join the next part of the trial.

During treatment

Up to 12 weeks

A total of 62 participants received either **secukinumab** or **placebo** during the trial. Each participant received an injection on Day 1 and Weeks 1, 2, 3, 4, 8 and 12.

Secukinumab, 300 mg	**Placebo**
30 participants	32 participants

All participants continued to receive standard treatment, including physical therapy and anti-inflammatory drugs.

After treatment

Up to 12 weeks after the last dose

Participants had safety follow-ups on Weeks 14, 18, 22, and 24.

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

What were the main results of this trial?

Did secukinumab help improve participants' rotator cuff tendinopathy symptoms?

The study team carefully reviewed all the results collected. However, because the trial ended earlier than planned, not enough participants took part to clearly show whether the treatment worked or not.

Researchers wanted to see if the signs and symptoms of participants' rotator cuff tendinopathy improved while taking **secukinumab**. For example, if they have less pain performing daily activities or better shoulder strength. To do this, they used a tool called the **Western Ontario Rotator Cuff (WORC) index**.

The WORC index is a questionnaire that measures how much shoulder problems affect everyday life. It has 21 questions that cover 5 areas of daily life:

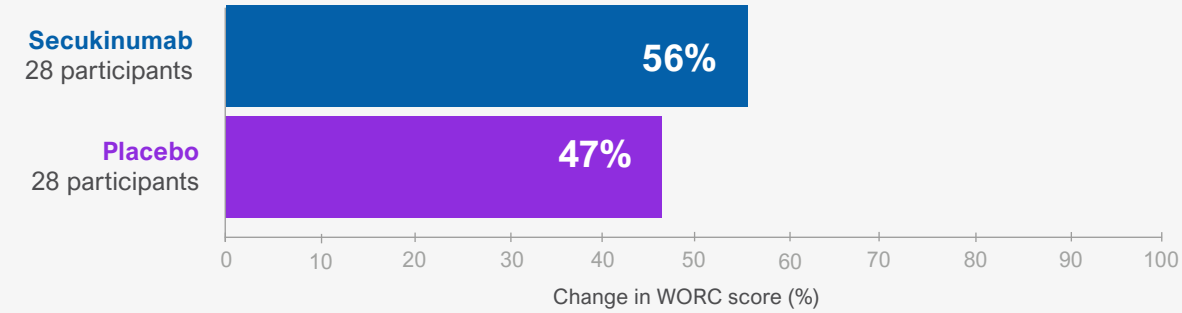
1. Physical symptoms like pain and weakness
2. Playing sports and staying active
3. Work and daily activities
4. Lifestyle, such as daily habits and routines
5. Emotions affected by shoulder problems

For each question participants rate how much their shoulder problem affects them. The scores from all 21 questions are added together and converted into a percentage. A higher WORC score means symptoms have less impact on daily life.

Each participant completed the questionnaire before, during, and after the 12-week treatment period. Researchers checked how much participants' WORC percentage scores changed from before treatment to Week 24 of the trial. They compared the change in WORC percentage scores between participants who received **secukinumab** and those who received **placebo**.

Only participants who had scores at the start of the trial and at Week 24 were included in the results. Results were available for 28 out of 30 participants in the **secukinumab** group and 28 out of 32 participants in the **placebo** group.

The graph below shows the average change in **WORC percentage scores** from the start of treatment to Week 24. Overall, the change in scores was similar between the **secukinumab** group and the **placebo** group. Because only a small number of participants took part, the researchers could not tell if this difference was meaningful or just happened by chance.



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 treatment up to 12 weeks 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 **52 out of 62 participants (84%)** had adverse events, including serious and other adverse events.

- **5 out of 62 participants (8%)** had adverse events that were considered serious.
- **1 out of 62 participants (2%)** left the trial due to an adverse event.
- **None** of the participants died.

There were no new or unexpected safety concerns with **secukinumab**.

How many participants had adverse events?

Participants who:	**Secukinumab** 30 participants	**Placebo** 32 participants
Had any adverse event, **including serious and other**	24 of 30 **(80%)**	28 of 32 **(88%)**
Had at least **1 serious adverse event**	2 of 30 **(7%)**	3 of 32 **(9%)**
Left the trial due to an adverse event	0 of 30 **(0%)**	1 of 32 **(3%)**

What serious adverse events did the participants have?

The table below shows all the serious adverse events that happened during the trial. Some participants had more than 1 event.

	Secukinumab 30 participants	Placebo 32 participants
Depression	1 of 30 **(3%)**	0 of 32 **(0%)**
Higher levels of the enzyme lipase, which can be a sign of problems in the pancreas Lipase increased	0 of 30 **(0%)**	1 of 32 **(3%)**
Stroke affecting the back part of the brain, which can cause vision problems Occipital lobe stroke	0 of 30 **(0%)**	1 of 32 **(3%)**
Fungal infection in the mouth or throat Oropharyngeal candidiasis	1 of 30 **(3%)**	0 of 32 **(0%)**
Pancreatic cancer Pancreatic neuroendocrine tumor	0 of 30 **(0%)**	1 of 32 **(3%)**
Blood clot in the heart Paradoxical embolism	0 of 30 **(0%)**	1 of 32 **(3%)**
Opening or splitting of the stitched area at the top of the vagina after womb removal Vaginal cuff dehiscence	0 of 30 **(0%)**	1 of 32 **(3%)**

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. Some participants had more than 1 event.

	Secukinumab 30 participants	Placebo 32 participants
Headache	8 of 30 **(27%)**	6 of 32 **(19%)**
Joint pain Arthralgia	3 of 30 **(10%)**	11 of 32 **(34%)**
Inflammation of the nose and throat Nasopharyngitis	5 of 30 **(17%)**	7 of 32 **(22%)**
Back pain	4 of 30 **(13%)**	3 of 32 **(9%)**
COVID-19	4 of 30 **(13%)**	3 of 32 **(9%)**

What was learned from this trial?

This trial helped researchers learn more about **secukinumab** when given to people with moderate to severe **rotator cuff tendinopathy**.

The trial's purpose was to see if **secukinumab** could help improve shoulder symptoms after 12 weeks of treatment.

The researchers concluded that:

- Because the trial ended earlier than planned, not enough participants took part to clearly show whether the treatment worked or not. This means they could not make a clear conclusion on whether **secukinumab** improved shoulder symptoms better than **placebo**.
- No new or unexpected safety concerns with **secukinumab** were found.

At the time this summary was written, the sponsor had no plans for future trials of **secukinumab** in people with **rotator cuff tendinopathy**.

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 **CAIN457FDE05**

For more information about this trial go to this website:

clinicaltrials.gov – search using the number **NCT05569174**

clinicaltrialsregister.eu/ – search using the number **2022-001516-26**

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, double-blind, placebo-controlled, parallel group, multicenter, 24-week study investigating the efficacy and safety of secukinumab compared to placebo in adult patients with moderate to severe rotator cuff tendinopathy and failure to conventional therapy "UnchAIN"

NOVARTIS

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