

The safety of AIN457 and its effects on shoulder tendinopathy



Thank you!

Thank you to the participants who took part in the clinical trial for the trial drug **AIN457**, also called secukinumab. All of the participants helped the researchers learn more about how well AIN457 works and how safe it is to take.

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. An independent organization prepared this summary of the trial results.

We hope this helps the participants understand their important role in medical research.

Trial information

Trial number: CAIN457X2201

Drug studied: AIN457 (secukinumab)

Sponsor: Novartis

This clinical trial at a glance

What was the purpose of this trial?

[Read more on page 3](#)

The purpose of this trial was to learn:

- If the trial drug AIN457 could lower the impact of shoulder tendinopathy symptoms on people's daily lives, such as pain and their ability to work
- More about the safety of AIN457 for people with shoulder tendinopathy

Who was in this trial?

[Read more on page 4](#)



- 96 men and women were treated in this trial
- The participants were 22 to 66 years old and had shoulder tendinopathy

What trial treatments did the participants receive? [Read more on pages 4-5](#)



Each participant was assigned one of these trial treatments as injections:

- AIN457
- Placebo – looks like the trial drug but has no trial drug in it. Using a placebo helps researchers better understand the actual effects of a trial drug.

Before and during treatment, the participants were allowed to receive physical therapy and pain medicines, such as acetaminophen or ibuprofen.

What were the main results of this trial?

[Read more on pages 5-8](#)



- The participants in both treatment groups rated the impact of shoulder tendinopathy symptoms as lower after receiving their trial treatment. The participants who received AIN457 had about the same change as those who received the placebo.
- Most of the participants had medical problems during this trial. None were serious. A similar number of participants in each treatment group had medical problems. The most common medical problem was headache.

[Read about other results of this trial on page 9](#)



You can find **more information** about this trial by going to the websites listed on [page 10](#).

What was the purpose of this trial?

The purpose of this trial was to learn if AIN457 could lower the impact of the symptoms of **shoulder tendinopathy** on people's daily lives, such as pain and their ability to work. This trial was also designed to learn more about the safety of AIN457 for people with shoulder tendinopathy.

Researchers are looking for better ways to treat shoulder tendinopathy. Shoulder tendinopathy is damage or **inflammation** in the tendons of the shoulder. Tendons are tissues that connect muscle to bone.

AIN457 is a drug that lowers inflammation and is approved to treat some conditions that involve inflammation, such as certain types of arthritis.

Before a drug can be approved for doctors to prescribe for a specific health condition, researchers do many trials to find out how safe it is and how it works.

What is inflammation?

Inflammation is the body's reaction to injury. It can:

- Cause pain, redness, and swelling
- Help the body heal when it lasts a short time
- Damage tissue when it lasts a long time

The main questions this trial was designed to answer:

- Did AIN457 lower the impact of shoulder tendinopathy symptoms on the participants' lives?
- What medical problems did the participants have during this trial?
Keeping track of the medical problems helped to learn about the safety of AIN457.

How long was this trial?

This trial started in December 2017 and ended in October 2019.

Most participants took part in this trial for about 30 weeks. 8 participants did not complete this trial.

Who was in this trial?

96 participants received treatment during this trial – 56 men and 40 women. The participants were 22 to 66 years old. Their average age was 47.

Every participant had shoulder tendinopathy that:

- Started 6 weeks to 1 year before they received a trial treatment
- Was painful on at least 3 of the 7 days before they started the trial
- Wasn't well treated with physical therapy or common pain medicines, such as acetaminophen or NSAIDs. **NSAIDs**, such as ibuprofen, are medicines that lower inflammation and relieve pain.

A participant couldn't be in this trial if they had a previous surgery in the affected shoulder, received a steroid injection during the 8 weeks before trial treatment, or had an inflammatory condition such as rheumatoid arthritis.

This trial took place in Czech Republic, Germany, the Netherlands, the United Kingdom, and the United States of America.



Visit novctrd.com for more information about:

- Who could and could not be in this trial
- The participants in this trial, such as their age, gender, and race

Use trial number **CAIN457X2201** to find the scientific summary.

What trial treatments did the participants receive?



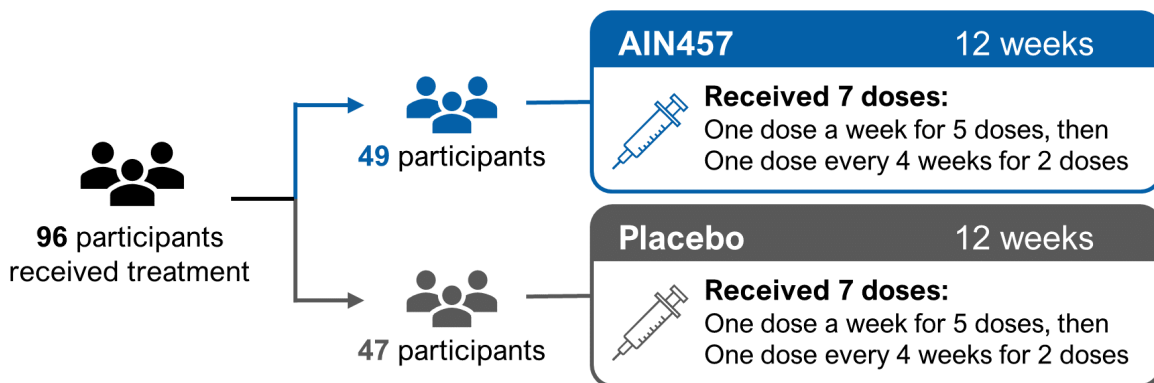
A computer program was used to randomly assign each participant the trial treatment they received:

- **AIN457:** 300 milligrams (mg)
- **Placebo:** A placebo looks like the trial drug but has no trial drug in it. Using a placebo helps researchers better understand the actual effects of a trial drug.

Using a computer program to assign the treatments helped make sure the team compared the results as fairly as possible.



The participants received their assigned treatment as injections.



The participants, sponsor staff, and trial staff did not know what trial treatment each participant received during the trial. Some trials are done this way because knowing what treatment participants receive can influence the results.

Not knowing what treatment participants receive helps make sure the results are looked at fairly.

During treatment, the participants could continue physical therapy and take certain amounts of common pain medicines.

What were the main results of this trial?



This is a summary of the overall results of this trial. Individual results from each participant may be different and are not included in this summary.

Researchers need many trials to learn if a drug or other trial treatment is safe and works well. Other trials may provide new information or different results. Always talk to a doctor before making any changes to your health care.

Did AIN457 lower the impact of shoulder tendinopathy symptoms on the participants' lives?



The participants in both treatment groups rated the impact of shoulder tendinopathy symptoms as lower after receiving their trial treatment. The participants who received AIN457 had about the same change as those who received the placebo.

To find this out, the trial staff asked each participant to answer a set of questions before they started treatment. For each question, a participant rated the impact of their shoulder tendinopathy on aspects of daily life, such as their pain and ability to work. Each participant answered the same set of questions several times during and after their 12 weeks of treatment.

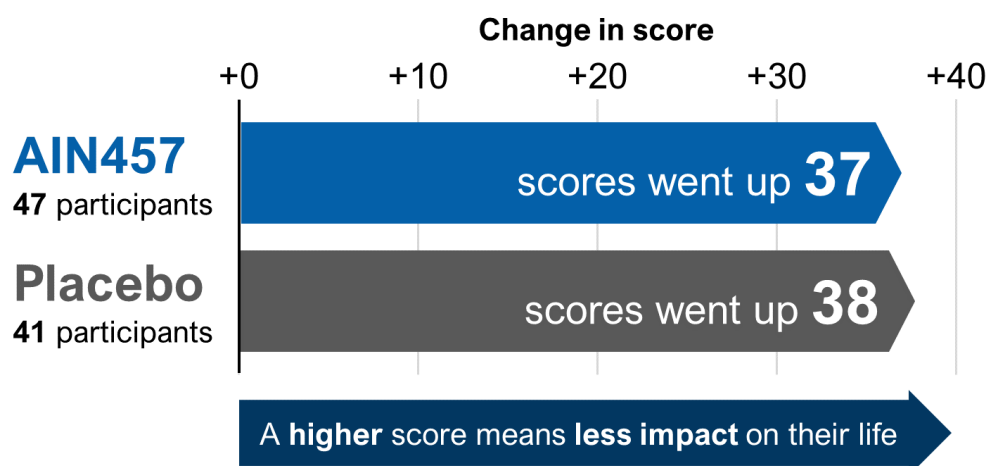
The clinical trial team combined each set of the participant's ratings into a single score called the **Western Ontario Rotator Cuff (WORC) score**. For this trial, a participant's WORC score ranged from 0 (most impact on their life) to 100 (no impact on their life).

The team looked at how much each participant's WORC score changed before, during, and after treatment. Then, the team compared this change between participants who received AIN457 and those who received the placebo.

On average, the participants who received AIN457 had about the same change in their WORC scores as those who received the placebo. This was true each time the participants answered the questions about the impact of their shoulder tendinopathy.

Change in WORC score at 14 weeks

The average change in how the participants' rated the impact of their shoulder tendinopathy compared to before they started treatment



Note: This graph doesn't include results from certain participants, such as those who had to take stronger pain medicines. The researchers couldn't be sure if the change in their WORC score was due to these stronger pain medicines or their trial treatment.

What medical problems did the participants have during the trial?

Medical problems that happen during trials are called “adverse events”. Trial doctors looked for any adverse events during the visits to the trial site. The participants also reported adverse events. This section includes the adverse events that happened during and after trial treatment.

Many trials are needed to know if a drug or treatment causes an adverse event. Trial doctors keep track of all adverse events that happen in trials, even if they do think the adverse events might not be related to the trial treatments.

What is an adverse event?

- An **adverse event** is any unwanted sign or symptom that the participants have during a trial
- It is 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 the trial treatments



Most of the participants had adverse events during this trial. None were considered serious. A similar number of participants in each group had adverse events. The most common adverse event was headache.

Participants who had adverse events

Participants who had:	AIN457		Placebo	
	Out of 49 participants		Out of 47 participants	
Serious adverse events	0%		0%	
Non-serious adverse events	73%		72%	
Left this trial due to adverse events	2%		0%	

What serious adverse events did participants have?


No serious adverse events were reported during this trial, including no deaths.

What non-serious adverse events did participants have?

Most of the participants had adverse events that were not serious. The table below shows the adverse events that happened to **5 or more participants**. Other adverse events were reported by fewer participants.

Non-serious adverse events

	AIN457 out of 49 participants		Placebo out of 47 participants	
Headache	14% 7 of 49		15% 7 of 47	
The common cold Nasopharyngitis	16% 8 of 49		11% 5 of 47	
Feeling sick to the stomach Nausea	12% 6 of 49		11% 5 of 47	
Upper respiratory tract infection Such as the common cold or flu	4% 2 of 49		9% 4 of 47	
Back pain	2% 1 of 49		9% 4 of 47	

 For more information about the adverse events the participants in this trial had, visit novctrd.com. Use trial number **CAIN457X2201** to find the scientific summary.

What other results were learned?

Did AIN457 affect the participants' shoulder tendons based on MRI images?

The trial doctors looked at each participant's shoulder tendons using **magnetic resonance imaging**, also called **MRI**. An MRI uses magnets to create a detailed picture of the inside of the body. The trial doctors looked for any changes in each participant's shoulder tendons based on the MRI images throughout the trial.

The clinical trial team found that AIN457 had no meaningful effect on the participants' shoulder tendons based on MRI images.

Did AIN457 affect the participants' shoulder tendinopathy based on other measures?

Each participant and their trial doctor answered other sets of questions to measure shoulder tendinopathy symptoms, including their:

- Ability to move their shoulder
- Shoulder pain
- General health
- Overall symptoms over the last 24 hours

The participants in both treatment groups had less severe symptoms over time. The participants who received AIN457 had about the same change as those who received the placebo.

What was learned from this trial?

This was the first trial to learn about how well AIN457 works for people with shoulder tendinopathy. The clinical trial team found that AIN457 had about the same effect as the placebo on the participants' shoulder tendinopathy symptoms. The team also found that about the same number of participants in each treatment group had adverse events.

This was one of many trials a drug must go through before it can be approved for doctors to prescribe for a specific health condition. This type of trial learns about how well a trial drug works and if there are any new safety concerns in a small number of participants.



The results presented here are for one trial. One trial cannot give a complete picture of the benefits and risks of a trial drug. The results of many trials are needed to find out which treatments can be used for people with shoulder tendinopathy. This summary shows only the main results from this trial. Other trials may provide new information or different results.

Where can I learn more about this and future clinical trials?



This is a summary of the results for one trial.

You can find detailed results and more information about this clinical trial on the Novartis Clinical Trial Results website:

1. Visit novctrd.com
2. Click on “Clinical Trial Results” at the top right of the page
3. Read and scroll down, then click “I accept” to agree to use the information and the website
4. Select “study number” from the drop-down menu
5. Type “**CAIN457X2201**” in the search box and click search

If you would like to view the website in a language other than English, you can click the “Google Translate” button on the top right of the page.

This trial was registered on the following websites:

- ClinicalTrials.gov – <https://clinicaltrials.gov/>
To find this trial, type **CAIN457X2201** in the **Other terms** search box
- European Union Clinical Trials Register – <https://www.clinicaltrialsregister.eu/ctr-search>
To find this trial, type **CAIN457X2201** in the search box



If you participated in the trial and have **questions** about the results, please speak with the trial doctors or staff at your trial site.

Full trial title:

A randomized, double-blind, placebo-controlled, parallel group, Phase II, 24-week study investigating the efficacy, safety and tolerability of AIN457 in patients with active overuse tendinopathy refractory to oral NSAIDs/acetaminophen, physiotherapy or corticosteroid injections

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

Thank you!

Novartis would like to thank all of the people who participated in this clinical trial. The participants made this clinical trial possible and helped researchers answer important health questions and learn about a possible medical treatment. Many volunteers and many clinical trials are needed to advance medical science.



Novartis is a global healthcare company based in Switzerland that provides solutions to address the evolving needs of patients worldwide.

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