

Clinical Trial Results Summary

A clinical trial to learn more about the effects of AIN457 given as an infusion into a vein in people with axial spondyloarthritis

Thank you!

Thank you to the participants who took part in the clinical trial for axial spondyloarthritis. 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 the trial with the participants and the public. We hope this helps the participants understand their important role in medical research.

Trial information

Trial number: CAIN457P12301

Drug studied: AIN457
(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 given as an infusion into a vein in people with ankylosing spondylitis or non radiographic axial spondyloarthritis compared to placebo.

Axial spondyloarthritis (axSpA) is a type of arthritis that causes inflammation in the joints and tissues that attach muscles to bones. It can also affect the eyes, skin, and gut organs. When the disease is active, it causes symptoms like back pain, feeling tired, joint pain, heel pain, sleep problems, and abdominal pain.

If the damage axSpA causes to the joints can be seen on an X-ray, it is called **ankylosing spondylitis (AS)**, and when that damage cannot be seen on an X-ray, it is called **non radiographic axSpA (nr axSpA)**.



AIN457, also called secukinumab, is an approved treatment for inflammatory conditions including axSpA in many countries when it is given as an injection under the skin. It blocks certain inflammation-causing proteins in the body, which helps reduce pain and can improve other symptoms related to inflammation, mobility, and quality of life.

In this trial, participants received **AIN457** as an infusion directly into a vein to find out if it can be used as a new treatment method for people with axSpA.



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.



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

- After 16 weeks of treatment, did more participants who received **AIN457** as an infusion into a vein have at least a 40% improvement in their axSpA symptoms compared to those who received a 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 December 2019 and ended in December 2022. It was planned for the participants to be in the trial for about 1 year and 2 months after starting the trial treatment.

Who was in this trial?



526 participants with **axSpA** – 413 with **AS** and 113 with **nr-axSpA** – entered this trial. Participants' ages ranged from 18 to 79 years. Their average age was 40 years. The number of participants by gender and race are shown below.

Gender

343 Men

183 Women

Race

42 American Indian or Alaska Native

106 Asian

13 Black or African American

7 Chinese

14 Indian

22 Korean

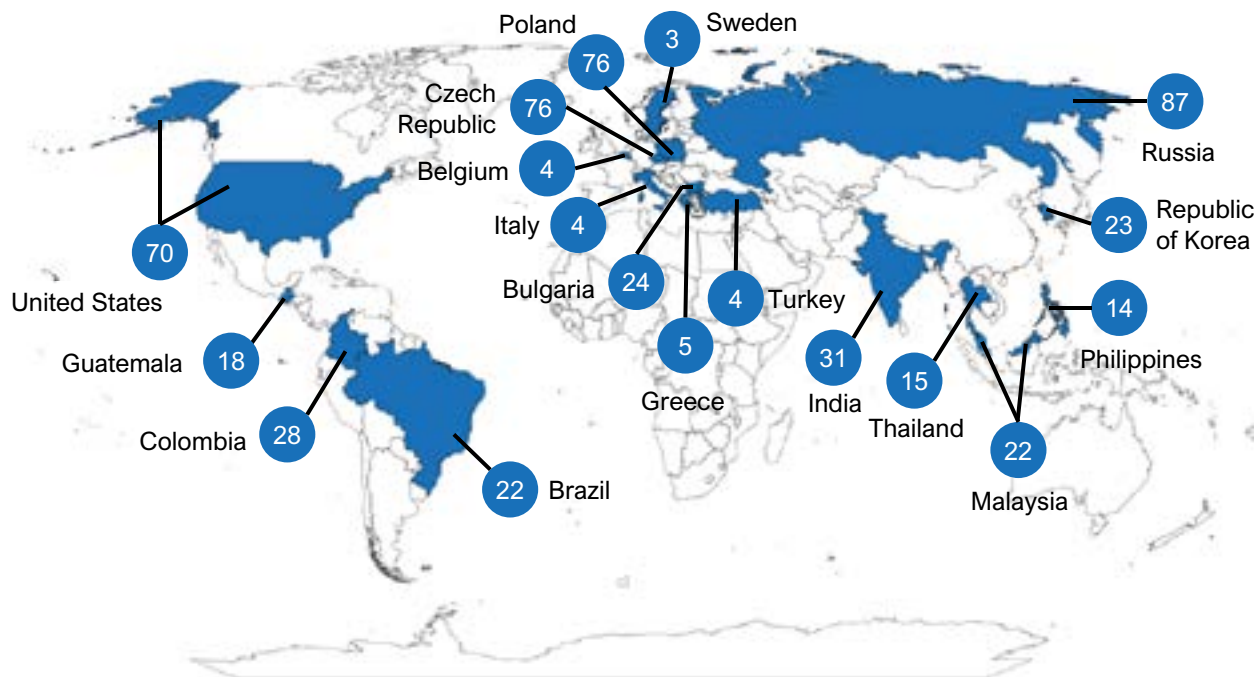
359 White

6 Multiple races

The participants could take part in this trial if they:

- Were at least 18 years old and were diagnosed with axSpA, either AS or nr-axSpA
- Had active axSpA despite using specific drugs for relief including non-steroidal anti-inflammatory drugs (NSAIDs)
- Did not have another ongoing inflammatory condition

526 participants from 18 countries entered the trial. The map below shows the number of participants who took part in each country.



What treatment did the participants receive?

The treatments in this trial were:



AIN457: Participants received **AIN457** as an infusion into a vein.



Placebo: Participants received a **placebo** as an infusion into a vein.

Researchers randomly assigned participants equally to either the **AIN457** group or the **placebo** group using a computer for the first 16 weeks of treatment. After that, all participants received **AIN457**.

None of the participants or trial doctors knew 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 10 weeks



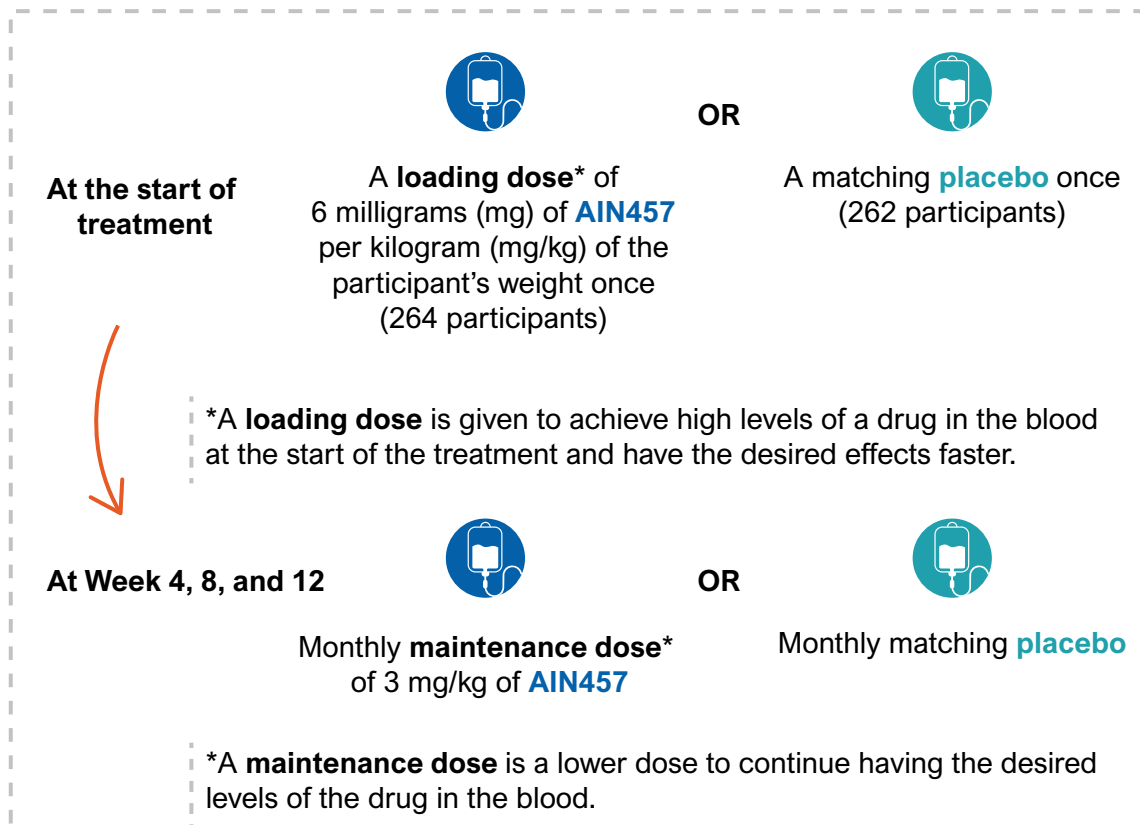
Trial doctors checked the participants' health and axSpA to ensure they could be in this trial.

During treatment

Up to 52 weeks

Treatment was divided into 2 periods:

Treatment Period 1 (16 weeks): 526 participants entered this period. Researchers randomly divided the participants to receive monthly infusions of either **AIN457** or a matching **placebo** through Week 12.



Treatment Period 2 (36 weeks): 506 participants who completed treatment Period 1 entered this period. They received monthly infusions of 3mg/kg of **AIN457** from Week 16 through Week 48.

Note: Participants could stop taking their treatment or leave the trial at any time.

Researchers closely monitored the overall health of all the participants throughout the trial.

After treatment

8 weeks



Researchers followed up on the participants' health until Week 60. Participants returned to their trial site at Week 60 for a health check-up and assessment of their symptoms.

What was the main result of this trial?

After 16 weeks of treatment, did more participants who received AIN457 as an infusion into a vein have at least a 40% improvement in their axSpA symptoms compared to those who received a placebo?



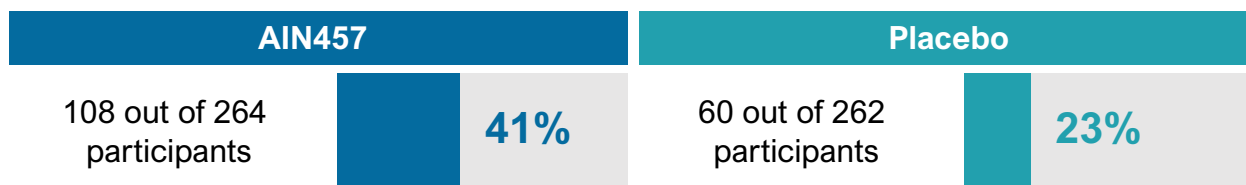
Yes, after 16 weeks of treatment, more participants who received **AIN457** as an infusion into a vein had at least a 40% improvement in their axSpA symptoms compared to those who received a **placebo**.

To answer this question, researchers checked whether the participants had the **ASAS40 response** at Week 16. They used complex tests to calculate the percentage of participants who had this response compared to the total number of participants in a group for whom the results could be analyzed.

What is ASAS40 response?

ASAS40 response means an improvement of at least 40% in the symptoms of axSpA based on several questionnaires that assess the level of pain and a person's ability to perform daily activities.

Percentage and number of participants who had at least a 40% improvement in their axSpA symptoms after 16 weeks of treatment



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 up to 12 weeks after receiving the last infusion.

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.

Note: Adverse events were reported for participants who received **AIN457** anytime during the trial and for those who received a **placebo** only for the first 16 weeks of the trial. Since all participants switched to **AIN457** after Week 16, more participants received **AIN457** than **placebo**. Therefore, participants were exposed to **AIN457** for a much longer time than to **placebo**.



327 of 517 participants who received **AIN457** and 105 of 261 participants who received **placebo** had adverse events. 1 participant who received **AIN457** died due to a heart attack. The researchers concluded there were no new safety concerns for **AIN457** for this trial compared to what was known from previous trials with **AIN457**.

How many participants had adverse events?

Participants who:	AIN457 517 participants	Placebo 261 participants
Had at least 1 adverse event	327 of 517 63%	105 of 216 40%
Had at least 1 serious adverse event	32 of 517 6%	3 of 216 1%
Stopped treatment due to an adverse event	18 of 517 4%	1 of 261 Less than 1%
Died during the trial	1 of 517 Less than 1%	0

What serious adverse events did the participants have?

Most serious adverse events that were reported during the trial happened in only 1 participant except the following that were reported in 2 (less than 1%) participants each who received **AIN457**:

- **a condition that causes inflammation and sores in the lining of the gut** (colitis ulcerative)
- **heart attack** (myocardial infarction)
- **skin infection** (cellulitis)
- **stomach pain** (abdominal pain)

What other adverse events did the participants have?

The table below shows the other adverse events that happened in **2% or more** participants in either group.

	AIN457 517 participants	Placebo 261 participants
COVID-19 infection	65 of 517 13%	10 of 261 4%
Common cold Nasopharyngitis	32 of 517 6%	7 of 261 3%
Infection of the nose and throat Upper respiratory tract infection	22 of 517 4%	6 of 261 2%
Joint pain Arthralgia	20 of 517 4%	1 of 261 Less than 1%
Diarrhea	18 of 517 3%	5 of 261 2%
Headache	17 of 517 3%	9 of 261 3%
Sore throat Pharyngitis	13 of 517 3%	1 of 261 Less than 1%
Feeling sick in the stomach Nausea	12 of 517 2%	2 of 261 Less than 1%
Stuffy nose Rhinitis	11 of 517 2%	2 of 261 Less than 1%
An infection of the urinary system Urinary tract infection	11 of 517 2%	1 of 261 Less than 1%

What was learned from this trial?

Researchers learned about the effects of **AIN457** given as an infusion into a vein in people with axSpA.



Researchers concluded that **AIN457** infusion for the treatment of axSpA was better than **placebo**. Researchers did not find any new safety concerns with the use of **AIN457** infusion compared to what was known from previous trials with **AIN457**.

Findings from this trial may be used to seek approval for **AIN457** infusion in people with axSpA.

Currently, there are no other trials planned with **AIN457** infusion for axSpA.

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 by study ID
CAIN457P12301

For more information about this trial, go to any of the following websites:

- www.clinicaltrials.gov search using the number **NCT04156620**
- clinicaltrialsregister.eu/ctr-search/search search using the number **2019-001177-90**

If more trials are planned, they will appear on the public websites above. When there, search for AIN457, secukinumab, ankylosing spondylitis, non-radiographic axial spondyloarthritis, or axial spondyloarthritis.

Full clinical trial title: A randomized, double-blind, placebo-controlled, parallel group, phase III multicenter study of intravenous secukinumab to compare efficacy at 16 weeks with placebo and to assess safety and tolerability up to 52 weeks in subjects with active ankylosing spondylitis or nonradiographic axial spondyloarthritis



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