NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about what happens to secukinumab in the body of people with giant cell arteritis or polymyalgia rheumatica

Thank you!

Thank you to the participants who took part in the clinical trial for **giant cell arteritis** and **polymyalgia rheumatica.** Every participant helped to learn more about the trial drug **secukinumab,** also called **AIN457.**

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: CAIN457E22101

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

Sponsor: Novartis

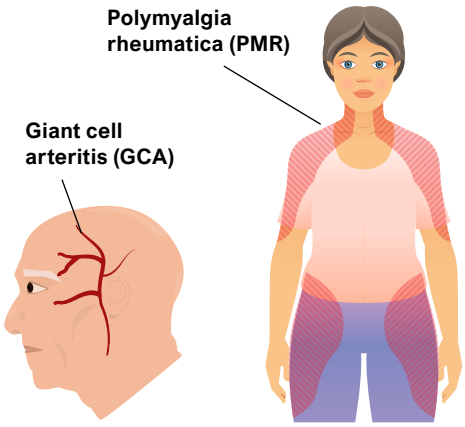
If you were a participant and have any questions about the results, please talk to your doctor or staff at the trial site.

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 purpose of this trial was to understand what happens to **secukinumab** when given into the bloodstream through a tube directly into the vein and to monitor participants' safety. This includes how the drug is absorbed, how it moves through the body, and how it is removed in people with **giant cell arteritis (GCA)** or **polymyalgia rheumatica (PMR)**.

GCA and **PMR** are types of inflammatory conditions. In **GCA**, the lining of the large blood vessels (arteries) becomes inflamed or swollen. **GCA** usually affects the arteries in the temples, which are the areas on each side of the forehead. Common symptoms of **GCA** include headaches, pain and tenderness in the scalp, jaw pain, and vision problems that can lead to blindness.



In people with **PMR**, their joints and muscles become weak, stiff, and painful, making it difficult to do daily activities. Most often, **PMR** affects the shoulders and hips.

The main treatment for **GCA** and **PMR** is steroids. However, using steroids for a long time can cause unwanted medical problems. There is a need for new medicines for treating these conditions.

Secukinumab, also called **AIN457**, is a type of **antibody** that blocks inflammation caused by a protein in our body called interleukin 17A (IL-17A). **Secukinumab**, given as an injection under the skin, is already approved in Europe and the United States for treating other inflammatory conditions, such as psoriatic arthritis.

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

Trial drug
AIN457 also called **secukinumab**

Pronounced as
se-koo-KI-noo-mab

In this trial, participants received **secukinumab** as an intravenous infusion (IV). An IV infusion is a slow drip through a tube directly into the vein. Researchers wanted to learn more about what happens to **secukinumab** in the body of people with **GCA** or **PMR** after multiple IV doses. This information will help researchers decide the right amount of **secukinumab** to give through an IV infusion for people with **GCA** and **PMR**.

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

- How much **secukinumab** was present in the blood after multiple doses?
- What medical problems, also called adverse events, happened during this trial?
  - ↳ **Adverse events** reported are any sign or symptom that participants had during this trial. Adverse events **may** or **may not** be caused by treatments in this trial.

How long was this trial?

The trial began in March 2024 and ended in April 2025. Each participant was in the trial for up to 28 weeks.

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

Who was in this trial?

65 participants received treatment in this trial, of which 34 participants had **GCA** and 31 had **PMR**. There were 39 females and 26 males. Participants' ages ranged from 54 to 86 years. Their average age was 72 years.

The table below shows the number of participants by race.

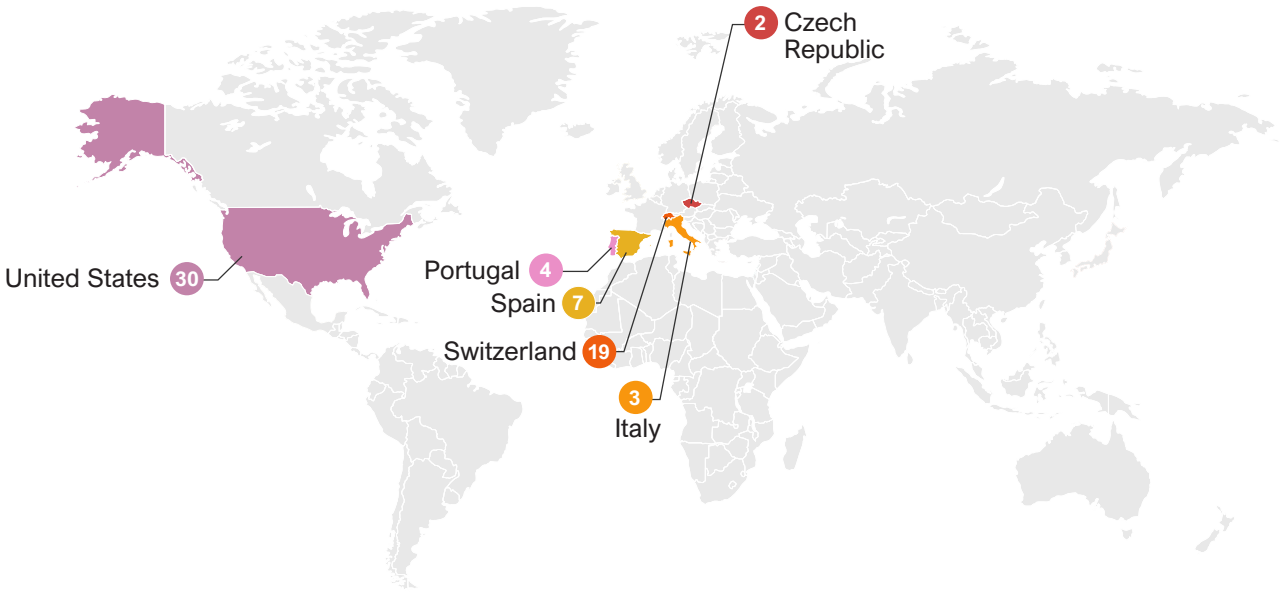
Race

63	White
1	Black or African American
1	Multiple

The participants could take part in this trial if they:

- Were 50 years of age or older when diagnosed with **GCA** or **PMR**.
- Had active **GCA** or **PMR** disease within 6 months of the start of the trial.
- Did not have other significant medical conditions that could affect the participant's safety.

65 participants from 6 countries received treatment. The map below shows the number of participants who took part in each country.



What treatments did the participants receive?

Secukinumab was given as an IV infusion at the following doses:

4 milligrams per kilogram of body weight (mg/kg) given once on Day 1. This was the loading dose. A loading dose is a higher first dose given at the start of treatment to quickly reach the amount needed in the body for it to work.

2 mg/kg given once at Week 4 and Week 8.

The participants, researchers, and trial staff knew that all participants received **secukinumab**.

What happened during this trial?

Before treatment

Up to 6 weeks

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

During treatment

Up to 12 weeks

A total of 65 participants received **secukinumab**:

GCA Group	PMR Group
34 participants	31 participants

Secukinumab was given as an IV infusion three times during the trial: once on Day 1, once at Week 4, and once at Week 8.

Trial staff performed regular blood tests during the treatment period to check how **secukinumab** moved through the body. They also recorded any medical problems participants had. Participants had up to 7 visits during the treatment period.

After treatment

Up to 8 weeks

After the 12-week treatment period, if participants' doctors thought they were benefiting from it, they could leave the trial and continue **secukinumab** given as injections under the skin.

For those participants who continued in the after treatment follow-up period, they had up to 2 follow-up visits during this time. The trial staff performed blood tests, checked participants' general health, and for any medical problems for up to 8 weeks until the end of the study.

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

What were the main results of this trial?

How much secukinumab was present in the blood after multiple doses?

After multiple IV infusions of **secukinumab**, researchers found that the blood levels of **secukinumab** in people with **GCA** or **PMR** were in the expected ranges known for **secukinumab**. The levels of **secukinumab** found in participants' blood was similar across both groups.

Researchers wanted to understand what happens to **secukinumab** in the bodies of people with **GCA** and **PMR** after multiple infusions. To study this, doctors collected blood samples from participants to measure the following:

- The highest and lowest concentration of **secukinumab** found in the blood
- The average concentration of **secukinumab** in the blood over time
- The total concentration of **secukinumab** found in the blood over time

Concentration is a measure of how much of the drug is in a certain amount of blood.

These measurements help researchers understand how **secukinumab** behaves in the body.

This information will help researchers decide how much **secukinumab** should be given through the IV infusion.

Out of the 65 participants who joined the trial, 55 were included in the results. This is because some participants did not receive all planned IV infusions and some stopped the treatment.

The researchers found that:

In both groups, the lowest **secukinumab** concentration found in the blood before infusion at Week 4 and Week 8 were similar. This indicates the body will have a constant concentration of **secukinumab** after infusion from Week 4 and onwards.

The highest concentration of **secukinumab** found in the body was slightly higher in the **PMR** Group than in the **GCA** Group due to the higher body weight in the **PMR** Group than in the **GCA** Group.

Overall, the concentration of **secukinumab** in the blood decreased similarly over time in both groups.

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 trial until the end of the trial, up to 28 weeks.

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, requires hospital care, or results in death

Treatments in the trial **may** or **may not** cause adverse events.

46 out of 65 participants had adverse events, including serious and other adverse events.

- **5 out of 65 participants** had serious adverse events.
- **1 out of 65 participants** died and this was not considered to be related to the treatment, but due to worsening of other medical conditions by the trial doctor.

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

What serious adverse events did the participants have?

5 participants had serious adverse events including one participant who died.

The table below shows all the serious adverse events that happened. One participant had 2 serious adverse events.

	GCA Group Secukinumab 34 participants	PMR Group Secukinumab 31 participants
Heart stops beating Cardiac arrest	1 of 34 (3%)	0 of 31 (0%)
Inflammation of the colon Colitis microscopic	1 of 34 (3%)	0 of 31 (0%)
Condition that affects the white matter in the brain Leukoencephalopathy	1 of 34 (3%)	0 of 31 (0%)
Suicidal thoughts Suicidal ideation	0 of 34 (0%)	1 of 31 (3%)
Worsening of GCA GCA	1 of 34 (3%)	0 of 31 (0%)
High blood pressure Hypertension	1 of 34 (3%)	0 of 31 (0%)

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

The table below shows the most common other adverse events in each treatment group.

	GCA Group Secukinumab 34 participants	PMR Group Secukinumab 31 participants
Worsening of GCA GCA	3 of 34 (9%)	0 of 31 (0%)
Worsening of PMR PMR	0 of 34 (0%)	3 of 31 (10%)
Infection of the nose and throat Upper respiratory tract infection	2 of 34 (6%)	1 of 31 (3%)
Joint pain Arthralgia	2 of 34 (6%)	1 of 31 (3%)
Muscle spasms	2 of 34 (6%)	1 of 31 (3%)

What was learned from this trial?

Researchers learned about what happens to **secukinumab** in the body of people with **giant cell arteritis** or **polymyalgia rheumatica** after multiple IV doses.

The researchers concluded that:

- The average **secukinumab** concentrations and how they decline over time were similar across both groups.
- Overall, the way **secukinumab** behaves in the body was similar in both groups.
- There were no unexpected safety concerns for **secukinumab** in this trial.

At the time this IV trial was conducted, other studies of **secukinumab** given as an injection under the skin were ongoing.

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:

Go to www.novctrd.com → Click **Clinical Trial Results** → Accept the terms **I accept** → Search for **CAIN457E22101**

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

- clinicaltrials.gov – search using the number **NCT06130540**
- euclinicaltrials.eu – search using the number **2023-507667-19-00**

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

Full clinical trial title: An open-label, multicenter study to evaluate the pharmacokinetics, safety and tolerability of intravenous secukinumab infusion in adults with giant cell arteritis (GCA) or polymyalgia rheumatica (PMR)

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1-888-669-6682 (US); +41-61-324 1111 (EU)
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