

Clinical Trial Results Summary

A clinical trial comparing the effects of secukinumab versus guselkumab in clearing plaque psoriasis

Protocol number: CAIN457A2403

Thank You!



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. Thank you for taking part in this trial for the drug AIN457, also known as secukinumab. You helped researchers learn more about how secukinumab works in people with plaque psoriasis.

As a clinical trial participant, you belong to a large community of people around the world. Your invaluable contribution to medicine and healthcare is greatly appreciated.

This summary only shows the results of a single clinical trial. Other clinical trials may have different findings. Researchers and health authorities, such as the Food and Drug Administration (FDA) in the United States and the European Medicines Agency (EMA) in Europe, look at the results of many clinical trials to understand which drugs work and if they are safe. It takes many people in multiple clinical trials around the world to advance medical science and healthcare. If you have any questions about these trial results, please talk to the doctor or staff at your trial site.

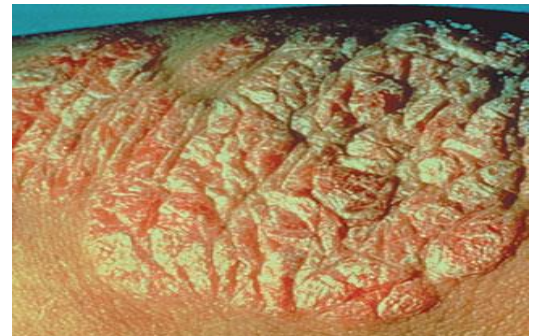
How long was this trial?

This trial was designed so that an individual participant could take part for about 4 months. The trial started in January 2019 and ended in January 2020. The entire duration, from enrolling the first participant to the last participant completing the trial was about 1 year.

The researchers completed this trial as planned. When the trial ended, the researchers collected information on the trial treatments (secukinumab and guselkumab) and created a report of the trial results. This summary is based on that report.

Why was the research needed?

Researchers were looking for a better way to treat plaque psoriasis. Plaque psoriasis is a long-lasting skin condition and can result in patches of thick, red, raised skin covered with a white-colored buildup of dead skin cells called scales. These patches, which are called plaques or skin lesions, may be itchy and/or painful. Psoriasis most commonly affects the skin on the elbows, knees, and scalp, though it can happen on any part of the body.



Source: National Psoriasis Foundation
([psoriasis.org](https://www.psoriasis.org))

Currently, many treatment options are available for plaque psoriasis. However, these treatment options sometimes either do not work or are unable to completely clear the skin.

In this trial, researchers wanted to find out the effects of secukinumab (pronounced as se-cu-KIN-umab) compared to guselkumab (pronounced as gue-sel-KOO-mab) in treating plaque psoriasis, which remained active despite previous treatment with ustekinumab (pronounced as us-te-KIN-umab). Ustekinumab is an approved drug to treat plaque psoriasis and psoriatic arthritis. At the start of the trial, researchers selected one active plaque in each participant (called “target plaque”) to study the effects of the treatments given.

Trial drugs

The drugs given in this trial were:



AIN457, also known as secukinumab



Guselkumab

Both secukinumab and guselkumab are approved to treat plaque psoriasis and psoriatic arthritis. Both the drugs act by binding to different types of interleukins (IL). Interleukin is a type of protein that is produced in high levels in the body of psoriatic patients and cause inflammation and itch. Secukinumab binds to IL-17A and guselkumab binds to IL-23.

Throughout the trial, the participants were allowed to apply mild ointments on their skin as prescribed by their doctor.

Trial purpose

The main question the researchers wanted to answer in this trial was:

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How many participants who took secukinumab had a clear or almost clear target plaque after 16 weeks of treatment compared to guselkumab?

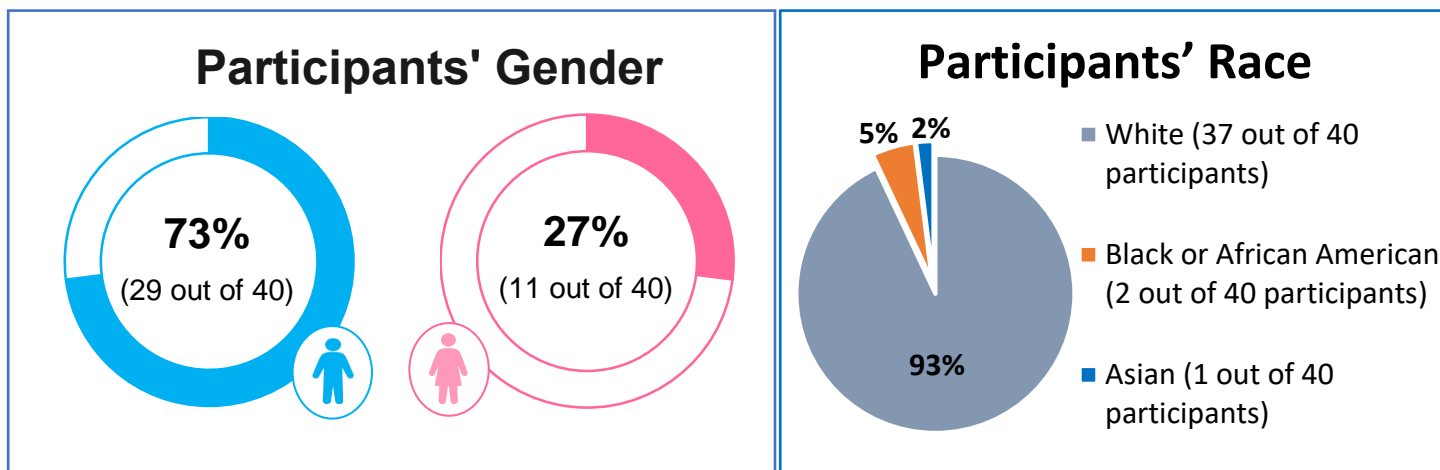
Who was in this trial?

The participants could take part in this trial if they:

- were 18 years of age or older and had long-term plaque psoriasis,
- had at least 1 active plaque that was not cleared after initial ustekinumab treatment,
- had moderate signs and symptoms of their plaque psoriasis at screening and the start of the trial.

A total of 40 participants from Canada, the United States (US), and Germany participated in this trial.

The average age of participants was 48 years. Participants' age ranged from 19 to 71 years. The majority of participants 73% (29 out of 40) were men. 93% (37 out of 40) of the participants were White, as shown in the below image.



What kind of trial was this?

This was an open-label trial, which means that both the researchers and the participants knew what treatment was given to participants.

What happened during this trial?

Before treatment

At the start of the trial (Day 1), one target plaque was selected. 2 skin biopsies were taken from all participants, one from the target plaque and one from a non-affected area.

During treatment

On Day 1, participants were randomly assigned to receive either secukinumab or guselkumab. This process is called randomization. This means that each participant had an equal chance of being assigned to any group.



Secukinumab: Participants self-injected two secukinumab, 150 milligrams (mg) injections at the start of the trial and then at Weeks 1, 2, 3, 4, 8, and 12.

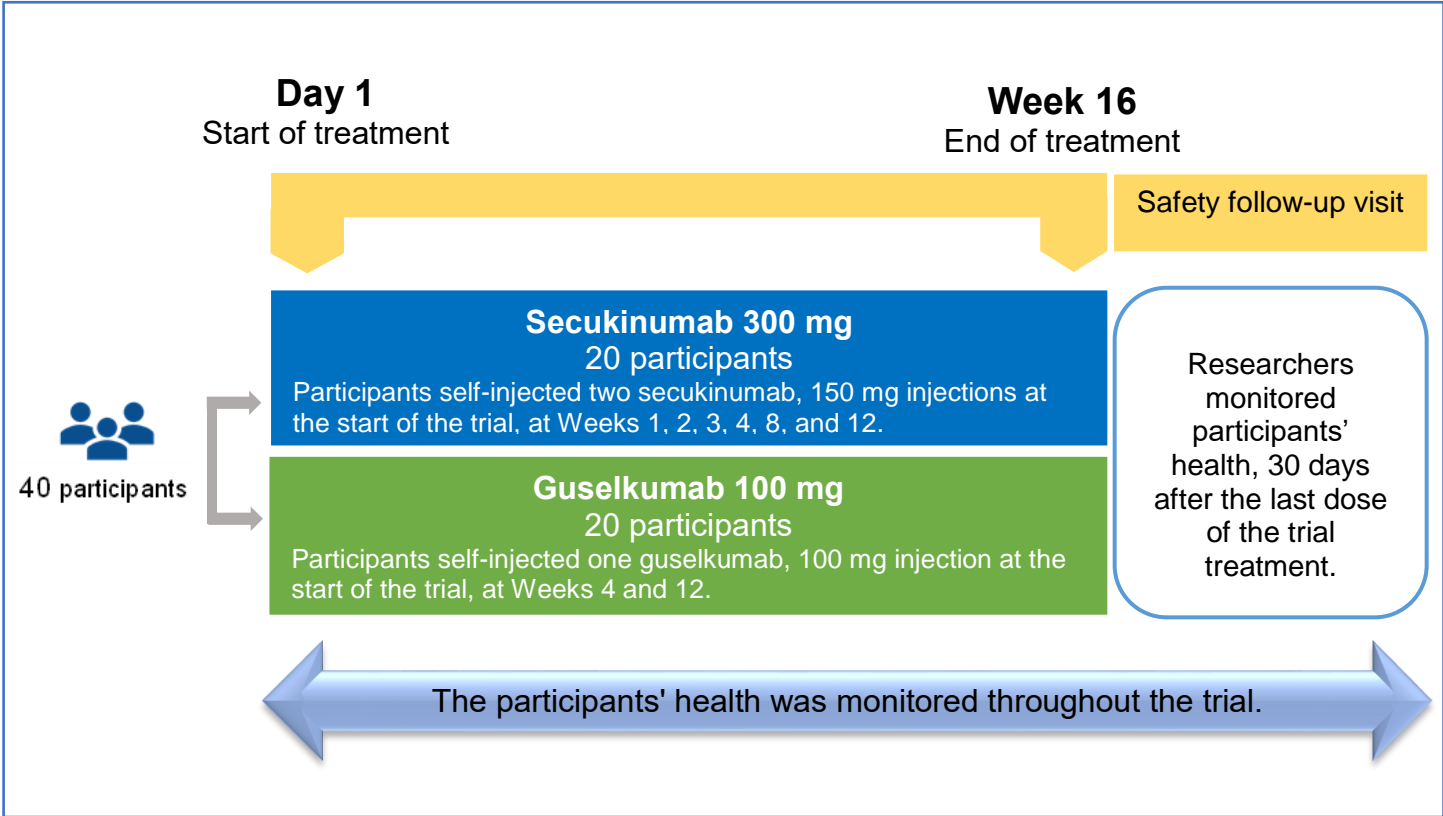


Guselkumab: Participants self-injected one guselkumab, 100 mg injection at the start of the trial and then at Weeks 4 and 12.

The target plaque was examined at the start of the trial and Week 16. Researchers examined the target plaque by looking at 3 parameters: skin redness, dry cracked or flaky skin, and thickness of the plaque.

At end of the trial visit, 1 skin biopsy was taken from the same area of the target plaque from where the sample was taken at the start of the trial. Researchers studied these skin samples to understand why certain plaques do not respond to treatment.

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

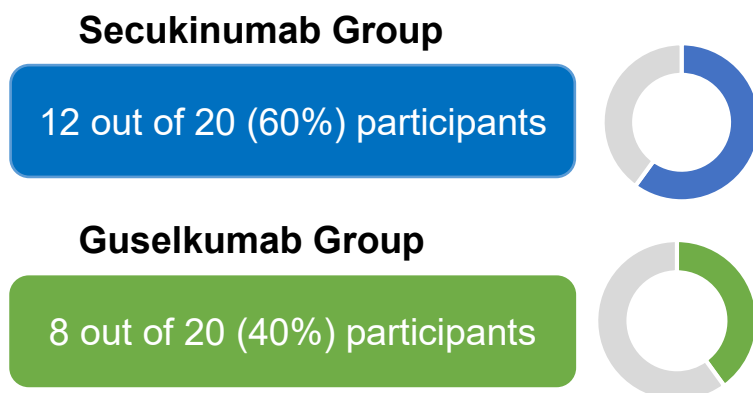


What were the key results of this trial?

This is a summary of the average results for all participants in different treatment groups. It does not show the results of each individual participant. Results of individual participants could be different from the results of the total group of participants. A detailed presentation of the results can be found on the websites listed at the end of this summary.

How many participants who took secukinumab had a clear or almost clear target plaque after 16 weeks of treatment compared to guselkumab?

After 16 weeks of treatment, more participants taking secukinumab had a clear or almost clear plaque compared with participants taking guselkumab. While a difference of 20% was observed between the 2 treatment groups, the results were not statistically significant. This means that the difference seen between the groups was not big enough to exclude the possibility that this might have happened by chance. Therefore, researchers could not confirm if secukinumab was better than guselkumab at treating the target plaque.



What medical problems did the participants have during the trial?

Medical problems that happen in clinical trials are called “adverse events”.

A lot of research is needed to know whether a drug causes an adverse event. During a trial, all adverse events are recorded, whether or not they are thought to be caused by the trial drug. When new drugs are being studied, researchers keep track of all adverse events participants have.

This section is a summary of the adverse events that happened during this trial. The websites listed at the end of this summary may have more information about all the adverse events that happened in this trial.



An adverse event is an unwanted sign, symptom, or disease that participants have during a trial.

An adverse event is considered “serious” when it is life-threatening, causes lasting problems, or the participant needs hospital care. These problems may or may not be caused by the trial drug.

How many participants had adverse events?

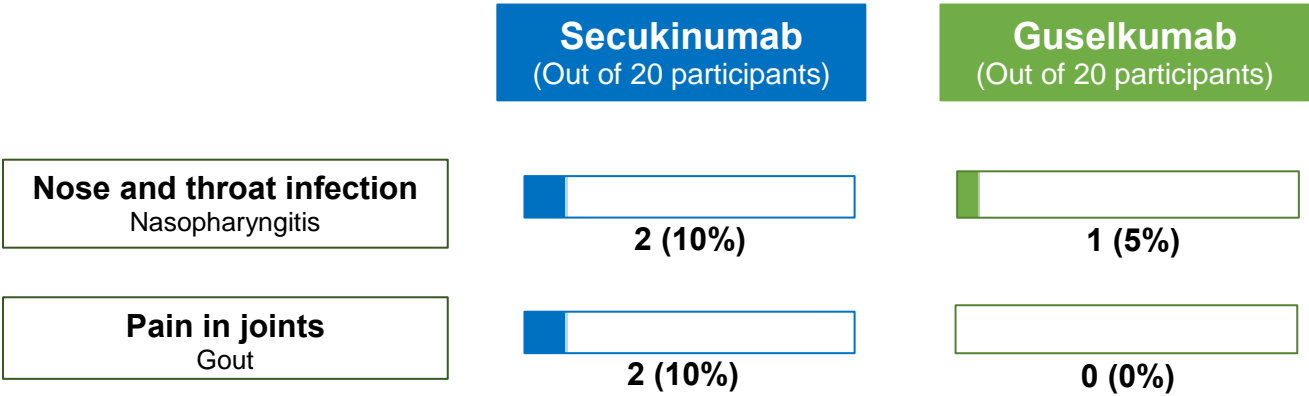
18 out of 40 participants (45%) had 1 or more adverse events. Serious adverse events happened in 3 out of 40 participants (8%) in the trial. No participant died during this trial. No participant stopped the trial drugs due to an adverse event.

Number of Participants (%) With Adverse Events

	Secukinumab (Out of 20 participants)	Guselkumab (Out of 20 participants)
At least 1 adverse event	12 (60%)	6 (30%)
At least 1 serious adverse event	2 (10%)	1 (5%)

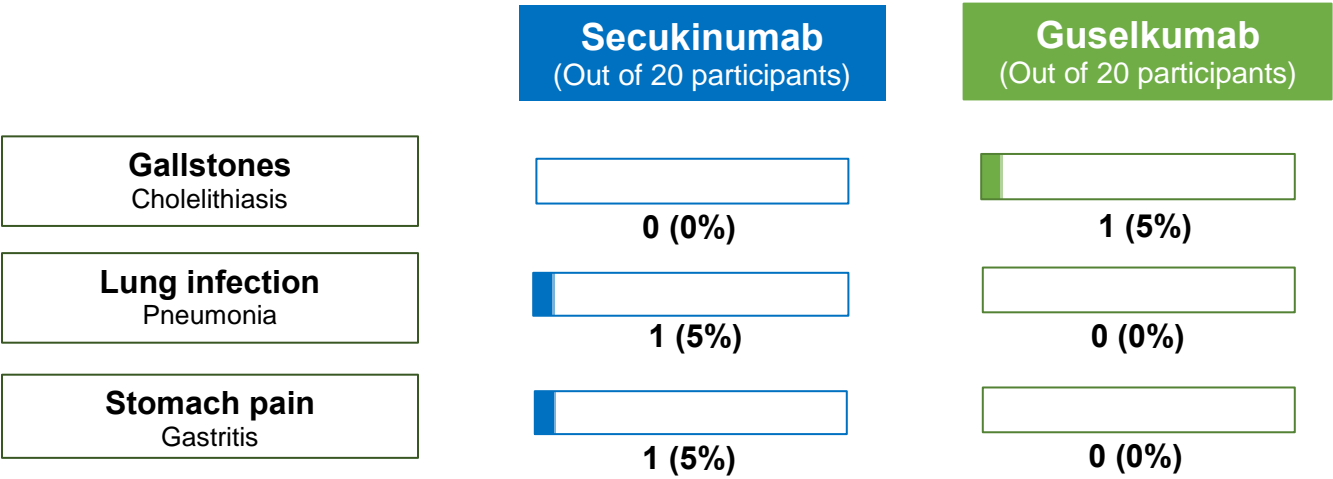
What were the most common non-serious adverse events?

The most common non-serious adverse events that happened in at least 10% of participants in any group are presented below:



What were the serious adverse events?

The serious adverse events that happened in any group are shown below:



How was this trial useful?

From this trial, researchers wanted to find out the effects of secukinumab compared to guselkumab in achieving clearance of plaque psoriasis, which remained active despite treatment with ustekinumab. Researchers found that more participants taking secukinumab had a clear or almost clear target plaque compared with participants taking guselkumab; however, the difference seen between the

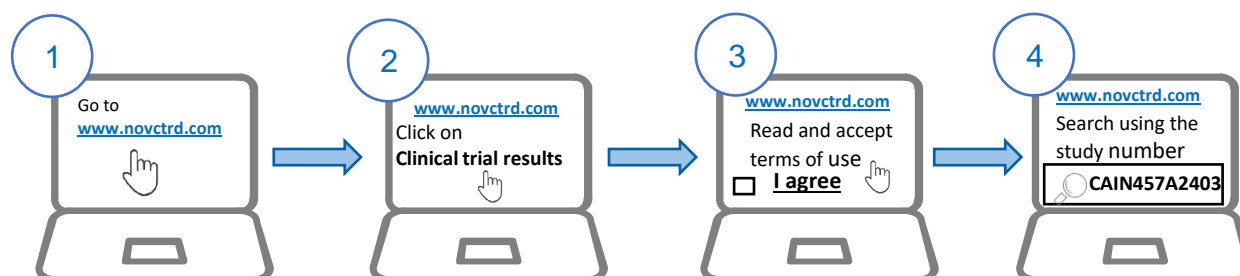
groups was not big enough to confirm if secukinumab was better than guselkumab at treating the target plaque. Researchers also found that both secukinumab and guselkumab were safe to use.

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

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).

Please follow the below steps:



You can find more information about this trial on the following websites:

- www.clinicaltrials.gov Use the NCT identifier NCT03553823 in the search field.
- <https://www.clinicaltrialsregister.eu/ctr-search/search> Use the EudraCT identifier 2018-001048-70 in the search field.

Full clinical trial title: A 16-week randomized, open-label, multicenter study to assess the superiority of secukinumab over guselkumab in the complete treatment of ustekinumab-resistant psoriatic plaques – ARROW

Thank you

Thank you for taking part in this trial. As a clinical trial participant, you belong to a large community of people around the world. You helped researchers answer important health questions and test new medical treatments.



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

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www.novartisclinicaltrials.com