

Clinical Trial Results



Research Sponsor: Novartis

Drug Studied: Secukinumab

National Clinical Trial #: NCT02267135

Protocol #: CAIN457AUS01

Trial Date: September 2014 to December 2015

Short Trial Title: A trial to test if secukinumab helps improve scalp psoriasis and is safe to use

Thank you!

As a clinical trial participant, you belong to a large community of participants around the world. You helped researchers answer important health questions and discover new medical treatments.

Thank you for taking part in the clinical trial for the drug secukinumab. You helped researchers learn more about how secukinumab works in people with chronic plaque psoriasis that affects their scalp.

Novartis, the sponsor of this trial, thanks you for your help and wants you to know the results of your trial. An independent non-profit organization called CISCRP and a medical writing organization called Synchrogenix prepared this summary of the trial results for you. We hope it helps you understand your important role in medical research.

If you have questions about the results, please speak with the doctor, research nurse, or other team member at your trial site.

What's happened since the trial ended?

This trial started in September 2014 and ended in December 2015. You were in this trial for about 6 months. However, the entire trial took a little over 1 year to complete.

The trial included 102 participants from 17 sites in the United States. When the trial ended the sponsor reviewed the data and created a report of the results. This is a summary of that report.



Why was the research needed?

Researchers were looking for a better way to treat plaque psoriasis on the scalp. Researchers wanted to see if a drug called secukinumab was safe to use and if it helped minimize psoriasis on your scalp. Researchers compared secukinumab with a placebo. A placebo looks like medicine, but does not have any real medicine in it.

The main questions researchers asked were:

- Did secukinumab help treat psoriasis on the scalp better than a placebo?
- Did secukinumab help in other ways?
- Did participants have medical problems during the trial?

To answer these questions, researchers asked for the help of men and women like you. All participants in this trial were between 18 and 69 years old. All had moderate to severe plaque psoriasis on their scalps for at least 6 months before entering this trial.

What kind of trial was this?

This was a “double-blind” trial. That means none of the participants, doctors, or staff knew what treatment each participant received. When the trial ended, the research sponsor found out which treatment participants had got so they could report the trial's results.

What happened during the trial?

Trial doctors did a full checkup of all participants. Some participants were already taking medications to treat their psoriasis, and those individuals were asked to slowly stop taking any medicine that would make it more difficult to test secukinumab.

This trial had 2 parts.

Part 1 lasted 12 weeks.

- Participants were randomly assigned, like flipping a coin, to take either 300 milligrams (mg) of secukinumab or a placebo.
- Participants went to a doctor's office and were injected with the medicine or the placebo into their skin.
- At Week 12, participants returned to the doctor's office to record if their scalp psoriasis had improved or not improved.

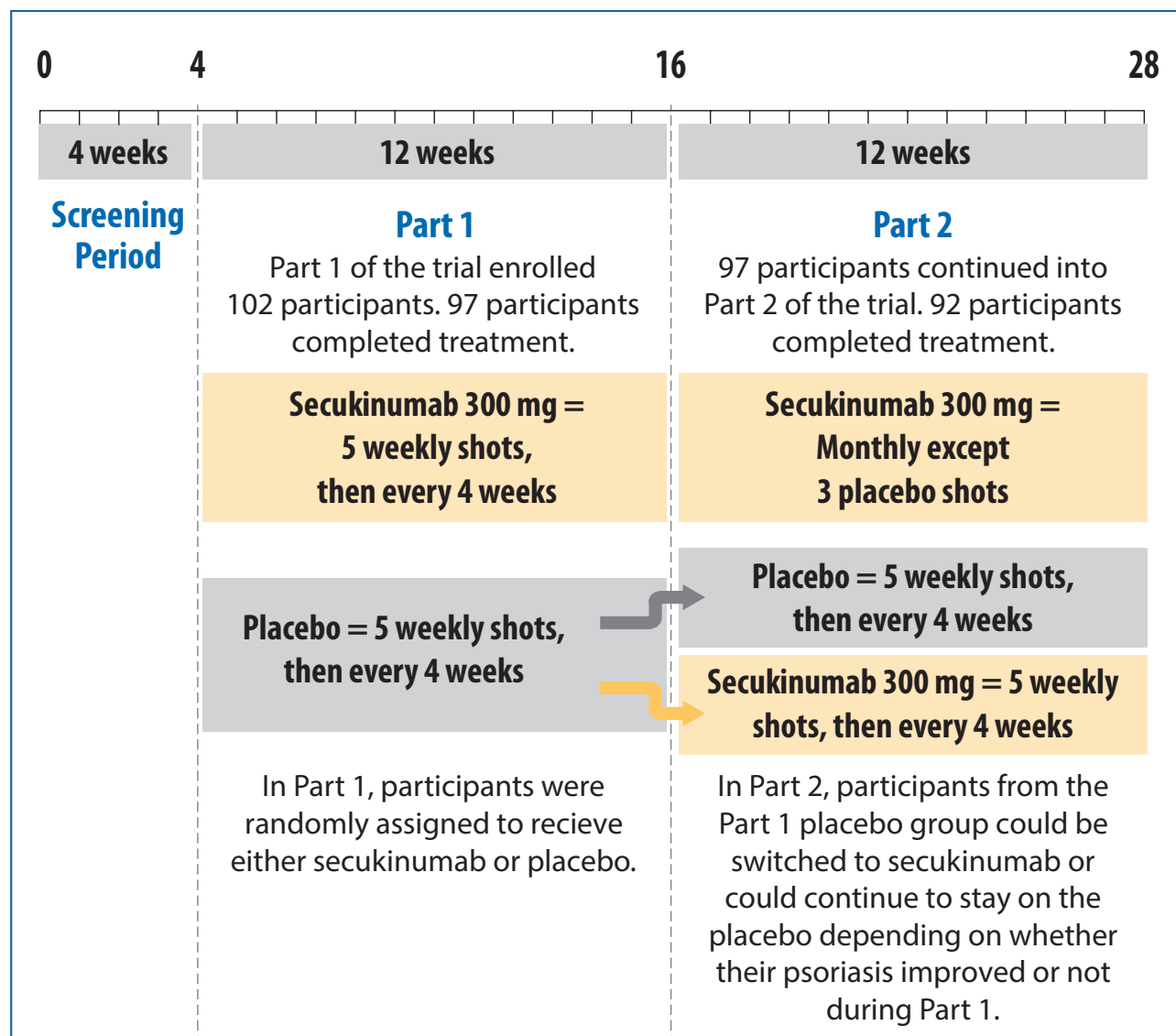
Part 2 also lasted 12 weeks.

In Part 2, all participants from Week 12 received the same number of shots (5 weekly injections and then once every 4 weeks).

- Participants who received placebo in Part 1, and whose scalp psoriasis did not improve enough after Part 1, were injected with secukinumab until the end of the trial.
- Participants who received placebo in Part 1, and whose scalp psoriasis did improve enough after Part 1, were injected with placebo until the end of the trial.
- Participants who received secukinumab in Part 1 received secukinumab every 4 weeks until the end of the trial. In addition, from Week 13 to Week 15, those participants also received weekly placebo shots. This was done so that both participants and study doctors did not know which treatment they were receiving (because everyone got the same number of shots). This did not impact the way secukinumab worked.

The chart below shows how long the trial lasted and what treatments participants got.

What Happened During the Trial?



What were the results of the trial?

This is a summary of the overall results and may not be the same for all participants. Researchers look at results of many studies to decide which drugs work best and are safer for participants. The results presented here are for a single trial. Other trials may provide new information or different results. You should not change your treatment based on the results of a single trial without first talking to your doctor.

Did secukinumab help treat psoriasis on the scalp better than a placebo?

Yes. Researchers used different tests to measure psoriasis symptoms. One test was called the Psoriasis Scalp Severity Index (PSSI). The PSSI measures the severity of your psoriasis, and your score was compared before you started the trial and again after 12 weeks of treatment. Researchers wanted to learn how many participants had at least 90% improvement of their scalp psoriasis after 12 weeks of treatment.

Another test was called the Investigator's Global Assessment, or IGA. It measured the severity of your scalp's psoriasis on a scale of 0 to 4, where 0 meant no sign of psoriasis, 1 meant almost no psoriasis, and 4 meant the psoriasis was severe. Researchers wanted to learn how many participants had no sign or almost no sign of psoriasis after 12 weeks of treatment.

The table below shows the PSSI and IGA results for participants in each group.

Relief of Psoriasis Symptoms after 12 Weeks of Treatment in Part 1

		Treatment Groups	
		Secukinumab 300 mg (out of 51 participants)	Placebo (out of 51 participants)
Psoriasis Scalp Severity Index (PSSI) Test	Participants with 90% improvement in scalp psoriasis	27 (53%)	1 (2%)
Investigator's Global Assessment (IGA) Test	Participants with no or almost no signs of psoriasis	29 (57%)	3 (6%)

Did secukinumab help in other ways?

Yes. Participants answered questions about their quality of life and psoriasis symptoms during the trial. Researchers found that participants who got secukinumab reported less itching, pain, and scaling at the end of Part 1 than participants receiving the placebo.

Did participants have medical problems during the trial?

Some participants did. A lot of research is needed to know whether a drug causes a medical problem, or “adverse event.” An adverse event is any sign or symptom that may or may not have been caused by the trial drug. So, when new drugs are being studied, researchers keep track of all adverse events that participants have.

How many participants had adverse events during the trial?

- 52 participants (51%) had adverse events in Part 1
- 39 participants (40%) had adverse events in Part 2
- 2 participants (2%) left the trial because of adverse events during Part 2

The table below shows how many participants had adverse events, how many had serious adverse events, and how many left the trial early due to an adverse event.

Adverse Events in this Trial

	Part 1		Part 2		
	Secukinumab 300 mg (out of 51 participants)	Placebo (out of 51 participants)	Secukinumab 300 mg (out of 50 participants)	Placebo/ Secukinumab 300 mg (out of 46 participants)	Placebo / Placebo (1 out of 1 participants)
How many participants had adverse events?	27 (53%)	25 (49%)	21 (42%)	18 (39%)	0 (0%)
How many participants had serious adverse events?	0 (0%)	1 (2%)	0 (0%)	0 (0%)	0 (0%)
How many participants left the trial due to an adverse event?	0 (0%)	0 (0%)	2 (4%)	0 (0%)	0 (0%)
Most Common adverse events: Common cold	3 (6%)	1 (2%)	--	---	---
Most Common adverse events: Skin rash caused by touching something	3 (6%)	2 (4%)	---	--	---
Most Common adverse events: Diarrhea	---	---	0 (0%)	3 (7%)	0 (0%)

How many participants had serious adverse events during the trial?

An adverse event is called “serious” when it is life threatening, causes lasting problems, or needs hospital care.

- No participants died during this trial.
- 1 participant (1%) from Part 1 of the trial experienced a serious adverse event. That participant was in the placebo group and developed cellulitis, an infection in the skin. Trial doctors did not think that the serious adverse event was related to the placebo.
- No participants had serious adverse events during Part 2 of the trial.

Where can I learn more about this trial?

Researchers look at the results of many studies to decide which drugs work best and are safer for patients. It takes volunteers in many trials all around the world to advance medical science.

A scientific summary of the results is available on the Novartis Clinical Trial Results website (www.novctrd.com). Once on the site, click “**Clinical trial results**” at the bottom of the page. Then, click “**I accept.**” After agreeing to enter the Novartis website, type **CAIN457AUS01** into the keyword search box and click “**Search.**”

If you have questions about the results, please speak with the doctor or staff at your trial site.

Official trial title: A randomized, double-blind, placebo-controlled, parallel-group, multicenter study to demonstrate the efficacy of subcutaneous secukinumab [300 mg] as assessed by the Psoriasis Scalp Severity Index (PSSI) at 12 weeks of treatment, compared to placebo, and to assess safety and tolerability up to 24 weeks in adult subjects with moderate to severe scalp psoriasis

Thank you

It is said that the greatest gift is one which is
given anonymously, giving when you do not know
whether you will get direct personal benefit.

This is the gift that you have given by taking part in a
clinical trial. It is a brave and selfless act, one that advances
medical knowledge and benefits public health.

Thank you for the gift of your participation in clinical research.



The Center for Information & Study on Clinical Research Participation (CISCRP) is a non-profit organization focused on educating and informing the public about clinical research participation. CISCRP is not involved in recruiting participants for clinical trials, nor is it involved in conducting clinical trials.

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