

Clinical Trial RESULTS



Research Sponsor: Novartis
Drug Studied: AIN457
U.S. National Clinical Trial #: NCT01358578
EudraCT #: 2010-022228-66
Protocol #: CAIN457A2303
Trial Date: June 2011 to July 2013

Thank you!

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

Thank you for taking part in the clinical trial for the drug AIN457, also called secukinumab. This trial started in June 2011 and was finished in July 2013. You and all of the 1,306 participants helped researchers find out if AIN457 helps adults with moderate to severe plaque psoriasis.

Novartis, the sponsor of this trial, thanks you for your help and thinks it is important for you to know the results of your trial. An independent non-profit organization called CISCRP prepared this summary of the trial results for you. We hope it helps you understand and feel proud of your important role in medical research. If you have questions about the results, please speak with the doctor or staff at your trial site.

WHAT'S HAPPENED SINCE MY TRIAL ENDED?

You were in the trial for up to 60 weeks, but the entire trial took more than 2 years to finish because some patients started the trial later than others. The trial had 1,306 participants at 154 sites in 23 countries in the European Union, Asia, North America and South America. When the trial ended in July 2013, the sponsor reviewed all 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. This is the most common type of psoriasis, a long lasting disease that mainly affects the skin. It causes areas of thick, red, raised skin called plaques. The plaques may be covered with silvery white buildup called scales, and may itch or feel sore.

In your clinical trial, researchers were studying a drug called AIN457, which may help relieve the symptoms of moderate to severe plaque psoriasis.

Researchers wanted to learn:

- Did AIN457 relieve psoriasis symptoms more than a placebo?
- Did AIN457 relieve psoriasis symptoms as much or more than psoriasis medicine that is already available?
- Did AIN457 still relieve psoriasis symptoms after 52 weeks?
- What medical problems did patients have during the trial?

To answer these questions, researchers asked for the help of people like you. All the people in your trial had moderate to severe plaque psoriasis for at least 6 months and were at least 18 years old.

WHAT KIND OF TRIAL WAS THIS?

This was a “double-blind” trial. This means none of the patients, trial doctors, or staff knew what treatment each patient received. Some trials are done this way because knowing what treatment you are getting can affect the results of the trial. When the trial ended, the research sponsor found out which treatment patients took so they could create a report of the results.

WHAT HAPPENED DURING THE TRIAL?

During the trial, patients got injections of the trial drug AIN457, another plaque psoriasis drug called etanercept, or a placebo. A placebo is a pill or liquid that looks real, but does not contain any real medicine. The trial staff gave you some injections, and you gave yourself some at home.

During the trial and at Week 52 the trial staff measured your psoriasis symptoms, took blood and urine samples, and did physical examinations.

Patients were put in 4 groups

150 milligrams (mg) of AIN457: If you were in this group, you got 150 mg of AIN457 once a week until Week 4, then every 4 weeks until Week 48.

300 mg of AIN457: If you were in this group, you got 300 mg of AIN457 once a week until Week 4, then every 4 weeks until Week 48.

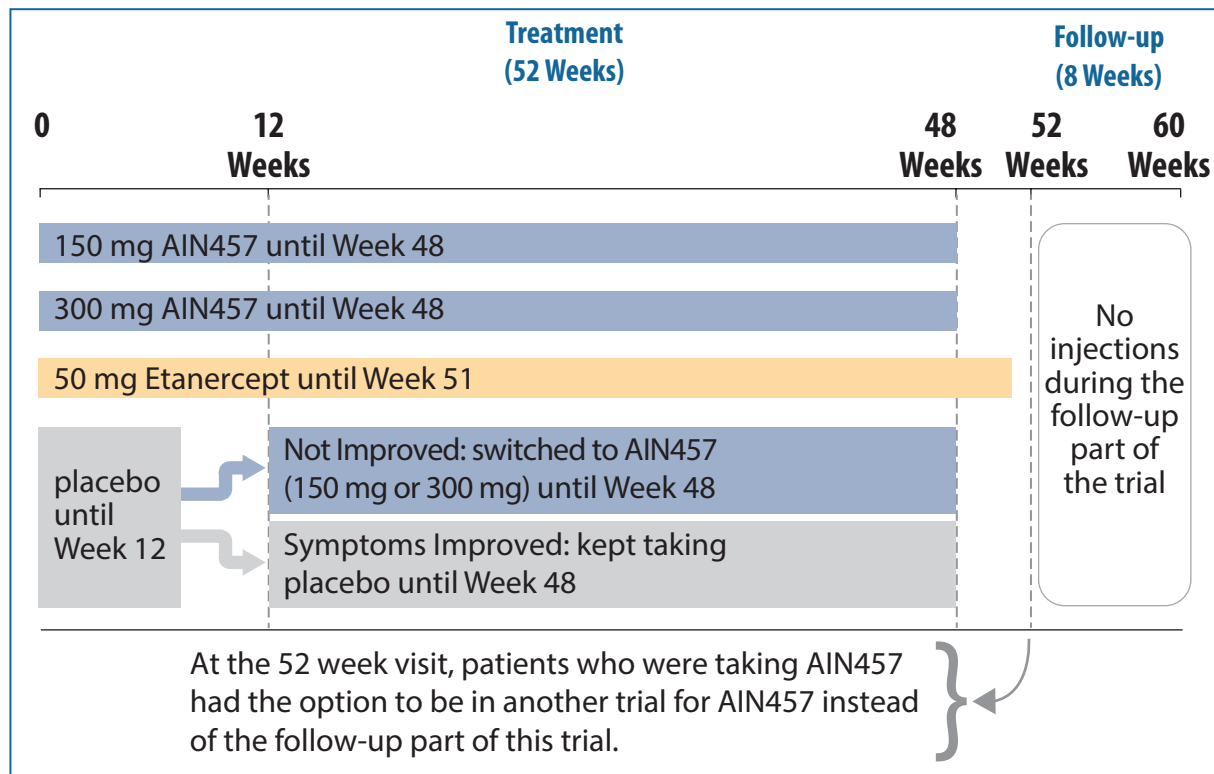
50 mg of etanercept: If you were in this group, you got 50 mg of etanercept twice a week until Week 12, then once a week until Week 51.

Placebo: If you were in this group, you got a placebo once a week until Week 4 and then once again at Week 8. If your symptoms improved after 12 weeks, you kept taking a placebo. If your symptoms did not improve, the trial staff switched you to 150 mg or 300 mg of AIN457, and you got it every week from Week 12 to Week 16, then every 4 weeks until Week 48.

Patients in the AIN457 groups and the etanercept group also got some placebo injections. This was done to make sure no one knew what treatment they got based on how often they got injections or what the injections looked like.

The chart below shows how long the trial lasted and what treatments patients got in each group.

What Happened During the Study?



After the Week 52 visit there were 8 weeks of follow-up. You did not get any injections, but the trial doctors and staff checked your health and looked for signs of psoriasis. Patients who took AIN457 had the option to be in another trial for AIN457 instead of the follow-up part of this trial.

WHAT WERE THE TRIAL RESULTS?

Did AIN457 relieve psoriasis symptoms more than a placebo?

Yes. In your trial, the 150 mg and 300 mg dose of AIN457 both relieved psoriasis symptoms more than the placebo after 12 weeks of treatment. Researchers used different tests to measure psoriasis symptoms.

One test was called the Psoriasis Area and Severity Index, or PASI. It measures how severe your psoriasis is in 4 body areas. Researchers wanted to learn how many patients had at least 75% less psoriasis and how many had at least 90% less psoriasis in these areas after 12 weeks of treatment.

The other test was called the Investigator Global Assessment, or IGA. It measures psoriasis from 0 to 4, where 0 means no sign of psoriasis and 1 means almost no signs of it. Researchers wanted to learn how many patients had no or almost no signs of psoriasis after 12 weeks of treatment. The table below shows how many patients in each group had these results.

Relief of Psoriasis Symptoms after 12 Weeks of Treatment: AIN457 Compared to the Placebo

Treatment Group	Psoriasis Area and Severity Index (PASI) Test		Investigator's Global Assessment (IGA) Test
	Patients with at least 75% less psoriasis	Patients with at least 90% less psoriasis	Patients with no or almost no signs of psoriasis
300 mg AIN457	249 of 323 patients (77.1%)	175 of 323 patients (54.2%)	202 of 323 patients (62.5%)
150 mg AIN457	219 of 327 patients (67.0%)	137 of 327 patients (41.9%)	167 of 327 patients (51.1%)
Placebo	16 of 324 patients (4.9%)	5 of 324 patients (1.5%)	9 of 324 patients (2.8%)

Did AIN457 relieve psoriasis symptoms as much or more than a psoriasis medicine that is already available?

Yes. In your trial, the 150 mg and 300 mg doses of AIN457 both relieved psoriasis symptoms more than etanercept after 12 weeks of treatment. The table below shows the results.

Relief of Psoriasis Symptoms after 12 Weeks of Treatment: AIN457 Compared to Etanercept

Treatment Group	Psoriasis Area and Severity Index (PASI) Test		Investigator's Global Assessment (IGA) Test
	Patients with at least 75% less psoriasis	Patients with at least 90% less psoriasis	Patients with no or almost no signs of psoriasis
300 mg AIN457	249 of 323 patients (77.1%)	175 of 323 patients (54.2%)	202 of 323 patients (62.5%)
150 mg AIN457	219 of 327 patients (67.0%)	137 of 327 patients (41.9%)	167 of 327 patients (51.1%)
Etanercept	142 of 323 patients (44.0%)	67 of 323 patients (20.7%)	88 of 323 patients (27.2%)

Did AIN457 still help patients with psoriasis after 52 weeks?

Yes. Most of the patients taking AIN457 still had at least 75% less psoriasis or still had no signs of psoriasis after 52 weeks. Researchers compared the results of patients taking AIN457 to patients taking etanercept. The table below shows how many patients who had relief of psoriasis symptoms after 12 weeks still had these results after 52 weeks.

**Continued Relief of Psoriasis Symptoms after 52 Weeks of Treatment:
AIN457 Compared to Etanercept**

Treatment Group	Psoriasis Area and Severity Index (PASI) Test	Investigator's Global Assessment (IGA) Test
	Patients who still had at least 75% less psoriasis at Week 52	Patients who still had no or almost no signs of psoriasis at Week 52
300 mg AIN457	210 of 249 patients (84.3%)	161 of 202 patients (79.7%)
150 mg AIN457	180 of 219 patients (82.2%)	113 of 167 patients (67.7%)
Etanercept	103 of 142 patients (72.5%)	50 of 88 patients (56.8%)

WHAT MEDICAL PROBLEMS DID PATIENTS HAVE?

A lot of research is needed to know whether a drug causes a medical problem. So when new drugs are being studied, researchers keep track of all medical problems that patients have. These medical problems are called “adverse events”. An adverse event is any sign or symptom occurring during treatment that may or may not be related to the trial drug.

How many patients had adverse events during the trial?

Some patients had adverse events during the trial and some left the trial because of adverse events. Some patients also had serious adverse events. An adverse event is considered “serious” when it is life-threatening, causes lasting problems, or needs hospital care.

The table on the next page shows how many patients had adverse events, how many had serious adverse events, and how many left the trial due to adverse events. It includes all patients who took 150 mg of AIN 457, 300 mg of AIN 457, 50 mg of etanercept, or a placebo during the first 52 weeks of the trial.

Adverse Events in the First 52 Weeks of the Trial

	Patients taking 150 mg of AIN457 (Out of 469 patients)	Patients taking 300 mg of AIN457 (Out of 467 patients)	Patients taking etanercept (Out of 323 patients)	Patients taking the placebo (Out of 327 patients)
Had adverse events	367 patients (78.3%)	376 patients (80.5%)	255 patients (78.9%)	168 patients (51.4%)
Had serious adverse events	24 patients (5.1%)	27 patients (5.8%)	20 patients (6.2%)	7 patients (2.1%)
Left the trial due to adverse events	9 patients (1.9%)	14 patients (3.0%)	12 patients (3.7%)	3 patients (0.9%)

What were the most common adverse events in this trial?

The table below shows the most common adverse events in your trial.

Most Common Adverse Events in the First 52 Weeks of the Trial

	Patients taking 150 mg of AIN457 (Out of 469 patients)	Patients taking 300 mg of AIN457 (Out of 467 patients)	Patients taking etanercept (Out of 323 patients)	Patients taking the placebo (Out of 327 patients)
Colds	107 patients (22.8%)	122 patients (26.1%)	87 patients (26.9%)	26 patients (8.0%)
Headaches	47 patients (10.0%)	59 patients (12.6%)	40 patients (12.4%)	24 patients (7.3%)
Diarrhea	36 patients (7.7%)	38 patients (8.1%)	22 patients (6.8%)	7 patients (2.1%)
Joint pain	32 patients (6.8%)	24 patients (5.1%)	23 patients (7.1%)	10 patients (3.1%)
Nose and throat infections	26 patients (5.5%)	26 patients (5.6%)	18 patients (5.6%)	3 patients (0.9%)
Back pain	20 patients (4.3%)	31 patients (6.6%)	27 patients (8.4%)	6 patients (1.8%)
Cough	16 patients (3.4%)	30 patients (6.4%)	12 patients (3.7%)	4 patients (1.2%)
Mouth and throat pain	20 patients (4.3%)	26 patients (5.6%)	10 patients (3.1%)	7 patients (2.1%)
Itching	21 patients (4.5%)	17 patients (3.6%)	16 patients (5.0%)	11 patients (3.4%)
Redness where the injection was given	0 patients (0.0%)	0 patients (0.0%)	17 patients (5.3%)	0 patients (0.0%)

WHERE CAN I LEARN MORE ABOUT THIS TRIAL?

A scientific summary of the results is available online on the Novartis Clinical Trial Results website (www.novartisclinicaltrials.com). After agreeing to enter the Novartis website, type CAIN457A2303 into the keyword search box and click “Go”. If you have questions about the results, please speak with the doctor or staff at your trial site.

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

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 patients for clinical trials, nor is it involved in conducting clinical trials.