Clinical Trial Summary

A clinical trial to test the trial drug CJM112 in patients with moderate to severe hidradenitis suppurativa

Thank you!

Novartis, the sponsor of this clinical trial, thanks the trial participants who helped make this clinical trial possible.

Overview of results

Protocol: CCJM112X2202

In this clinical trial, researchers studied how patients with a skin condition called hidradenitis suppurativa, or HS, responded to a drug named CJM112.

What you should know about clinical trials

A clinical trial is a type of research used to learn more about how our bodies respond to drugs or other treatments. Do not use the results of only one clinical trial to make decisions about your health care.

The researchers wanted to study:

- The effects of the trial drug CJM112 on the severity of HS during and after 16 weeks of treatment
- How much CJM112 got into patients' blood
- The effects of CJM112 on patients' immune system
- Any medical problems that patients reported during the clinical trial

Who was in this clinical trial?

66 male and female adults with moderate to severe HS started this clinical trial.

What type of clinical trial was this?

This study was a Phase 2 clinical trial. That means the clinical trial tested how well the trial drug CJM112 worked for people with HS.

How was safety tested?

Researchers looked for any medical problems, called adverse events, that happened during this clinical trial. Patients reported a number of adverse events, including 2 serious adverse events, a groin abscess and chest pain. The trial drug is not believed to have caused any serious adverse events.

What was learned in this clinical trial?

Researchers found that after getting high doses of CJM112 for 16 weeks, HS was less severe in patients and that CJM112 did not show safety concerns for the patients in this clinical trial.

Table of Contents

Overview of results	1
Why was this clinical trial needed?	2
What type of clinical trial was this?	3
What happened during this clinical trial?	4
What was learned in this clinical trial?	5
What medical problems did patients report?	7
How has this clinical trial helped?	9
Where can I learn more about this and future clinical trials?	9

Researchers need many clinical trials to learn if a medicine is safe and works well. This is a summary of the overall results of this clinical trial, not the results for each patient in the clinical trial.

Do not use the results of this clinical trial to make health care decisions. Always talk to a doctor before making any changes to your treatment.

Why was this clinical trial needed?

Researchers asked patients to help them test a trial drug named CJM112. Researchers wanted to learn about how CJM112 works in patients with hidradenitis suppurativa, which is also called HS.

Researchers are looking for a better way to treat patients with HS. HS is a long-term skin disease that causes boils or lumps most often in the armpits and groin. HS usually begins with boils, or lumps, under the skin that are also called lesions. At first, these look like pimples. Then, they often grow bigger and many fill with thick fluid (pus). HS can be painful, cause scars, and limit how people can use their arms and legs. Researchers don't know what causes HS, but think the immune system may have a role.

Our immune system is made of cells and proteins that can protect us from disease and infection. Researchers think that a protein in our body's immune system, called IL-17 might cause swelling (inflammation) that creates the boils or lumps of HS. Researchers wanted to learn if CJM112 can block IL-17 and decrease the severity of HS.

What is IL-17?

Il-17 is the name of one of the many proteins in our body. Researchers want to learn if IL-17 causes the swelling that creates the boils of HS.

In this clinical trial, researchers compared CJM112 to a placebo. A placebo looks like medicine but does not have any real medicine in it. Using a placebo helps researchers better understand the actual effects of a trial drug. A placebo is used so that no one in the clinical trial knows who got the trial drug or the placebo. In this clinical trial, the placebo was injected just like CJM112.

In this clinical trial, the researchers wanted to study:

- The effects of CJM112 on the severity of HS during and after 16 weeks
- How much CJM112 got into patients' blood
- The effects of CJM112 on patients' immune system
- Any medical problems that patients reported during the clinical trial

Who was in this trial?

The researchers recruited 66 adult patients – 22 male and 44 female – to begin the 44 week-long clinical trial. They hoped at least 60 would complete the first part of the clinical trial. All patients were between 18 and 65 years of age. The average age of patients was 37 years old.

Some patients dropped out of the clinical trial, so that by the end of the trial:

- 60 patients finished Period 1 that lasted 16 weeks
- 50 patients finished Period 2 that lasted 16 more weeks
- 49 patients finished a follow-up period that lasted 12 more weeks

Everyone in this trial had moderate to severe HS for at least one year before the trial began. All patients had received treatment for HS with antibiotics but no other treatment for HS within 4 weeks before joining this trial. Researchers conducted this trial with patients at 16 health care centers. Those centers were located in Denmark, Switzerland, Netherlands, United States, and Germany.

What type of clinical trial was this?

This was a Phase 2 clinical trial. Researchers tested how well this trial drug worked and looked for any medical problems that occurred in a small number of patients.

None of the patients, research staff, or sponsor staff knew which patients got CJM112 or a placebo. Some trials are done this way because knowing what treatment each patient got can affect the results of the trial. Doing a trial this way helps make sure the results are looked at fairly. When the trial ended, the research sponsor found out what all patients got so they could create a report of the trial results.

Each patient took part in the clinical trial for up to 44 weeks. They started at different dates during the trial. This trial began in April, 2015 and ended in November, 2016.

What happened during this clinical trial?

First, researchers randomly placed patients into groups using a computer program. This trial had 2 periods. Each period lasted 16 weeks. Then, there was a 12 week follow-up period. This trial tested both high doses and low doses of CJM112. Patients got CJM112 or the placebo by a needle placed under their skin.

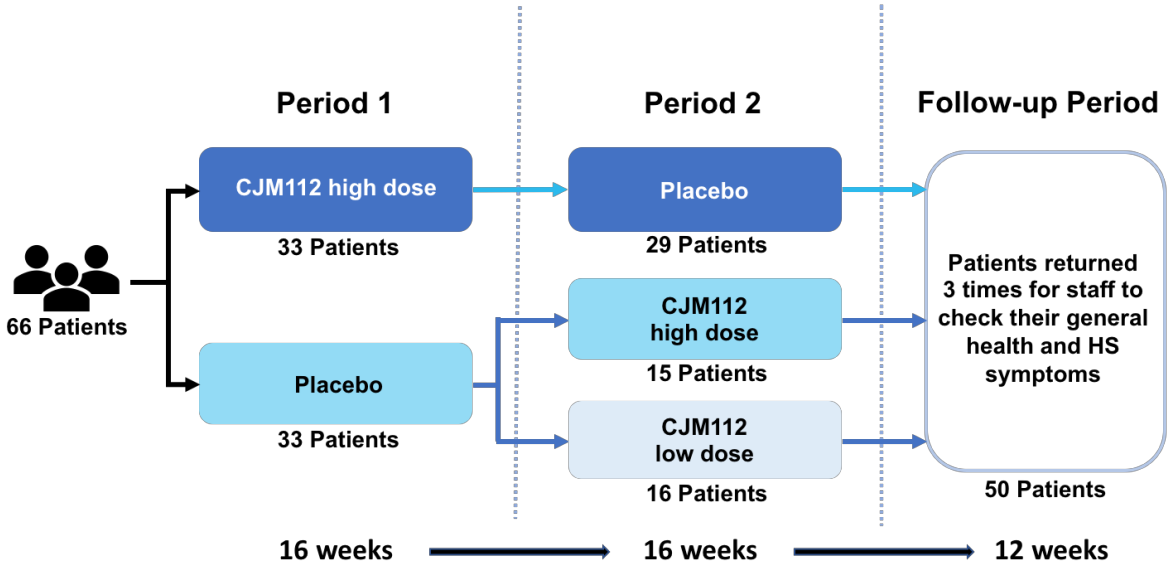
Period 1 lasted 16 weeks:

- 29 patients got 10 high doses of CJM112
- 31 patients got 10 doses of the placebo
- 6 patients did not complete Period 1

Period 2 lasted 16 weeks:

- From the group who got a high dose of CJM112 in Period 1, 22 patients got the placebo in Period 2
- From the group who got the placebo in Period 1:
  - 13 patients got 10 low doses of CJM112 in Period 2
  - 14 patients got 10 high doses of CJM112 in Period 2
- 11 patients did not complete Period 2

The figure below shows how this clinical trial was designed and the number of patients who started each period:



Follow-up period lasted 12 weeks:

- During this time patients returned 3 more times
- That allowed the researchers to learn how patients were feeling and how severe their HS was over time

During the entire trial, the research staff took blood samples and checked the patients' general health and HS symptoms.

What was learned in this clinical trial?

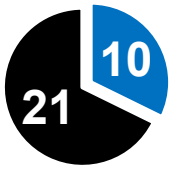
This is a summary of the overall results of this clinical trial, not the individual results of each patient in the clinical trial. This is a summary of only one clinical trial. Results presented here are for a single clinical trial. Do not use the results of only this clinical trial to make decisions about your health care. Always talk to a doctor before making changes to your treatment.

Main results

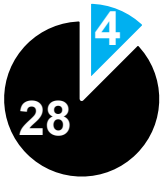
In this trial, researchers learned about the effects of CJM112 on the severity of HS during and after 16 weeks. Researchers measured the severity of HS at several times during this study by measuring patients' HS symptoms on a scale. A patient's severity had to lower by a certain amount for researchers to count their HS as less severe.

After 16 weeks of treatment, the severity of HS was lower for more patients who got CJM112 than for patients who got the placebo.

Number of patients with lower severity of HS after 16 weeks



10 of the **31** patients (32%) who got the **high dose of CJM112** had lower severity of HS.



4 of the **32** patients (13%) who got the **placebo** had lower severity of HS.

For some patients, the severity of HS decreased during the 16 week trial. After weeks 2, 4, and 12, the severity decreased for more patients who got CJM112 than for those who got the placebo. This difference was too small for researchers to know for sure that CJM112 caused it.

After week 8, the severity of HS decreased for slightly more patients who got the placebo compared to those who got CJM112.

Other key results

In this trial, researchers also learned:

- **The level of CJM112 in patients' blood.**
  Researchers collected samples of blood from patients during the trial to measure how much of the trial drug CJM112 got into their blood after each treatment. Researchers learned that the amount of CJM112 found in their blood was the amount expected for this type of trial drug.

- **The effects of CJM112 on patients' immune systems.**
  Our body has an immune system that helps protect us from disease and infection. One of the ways our immune system protects us is by creating proteins called antibodies. The immune system uses antibodies to defend against foreign things like a virus or bacteria. Sometimes, antibodies are formed against medicines like the trial drug CJM112 when it enters the body.

  In this trial, 1 patient who got the high dose of CJM112 developed antibodies that worked against CJM112. That seemed to have an effect on how CJM112 worked. Other patients in this trial also developed the same antibodies, but in those cases it did not seem to have an effect on how CJM112 worked.

  Antibodies against CJM112 did not cause any medical problems for any patients in this trial.

  The trial drug CJM112 was designed to interfere with how the immune system protein IL-17 works. IL-17 may play a role in increasing HS. Researchers tested how much IL-17 was in the patients' blood. The results of this early and small clinical trial confirmed that CJM112 did work as designed. More and larger studies are needed to confirm if this is always the case.

What medical problems did patients report?

Medical problems that occur during a clinical trial are called adverse events. An adverse event is any unwanted sign or symptom that patients have during a trial. These problems may or may not be caused by the clinical trial or the trial drug.

During this clinical trial, patients reported all adverse events to the researchers. Researchers kept track of all adverse events, whether or not they were caused by the trial drug.

Overall, 5 patients dropped out of this trial because of adverse events.

How many patients reported a serious adverse event?

An adverse event is considered serious when it is life-threatening, requires a hospital stay, can cause disability or permanent damage, or can cause a birth defect.

Two patients (3%) reported a serious adverse event during the trial while being given the placebo.

The two patients reported:

- A groin abscess – 1 patient developed a groin abscess during the trial and needed a hospital stay. A groin abscess is an infection under the skin between the belly and thigh that swells and often requires surgery.
- Chest pain – 1 patient reported chest pain that was caused by heart disease.

What is a placebo?

A placebo looks like medicine, but does not have any real medicine in it. Patients didn't know if they got CJM112 or a placebo.

The doctors who led this trial did not believe these serious adverse events were related to the trial drug.

What were the most common adverse events?

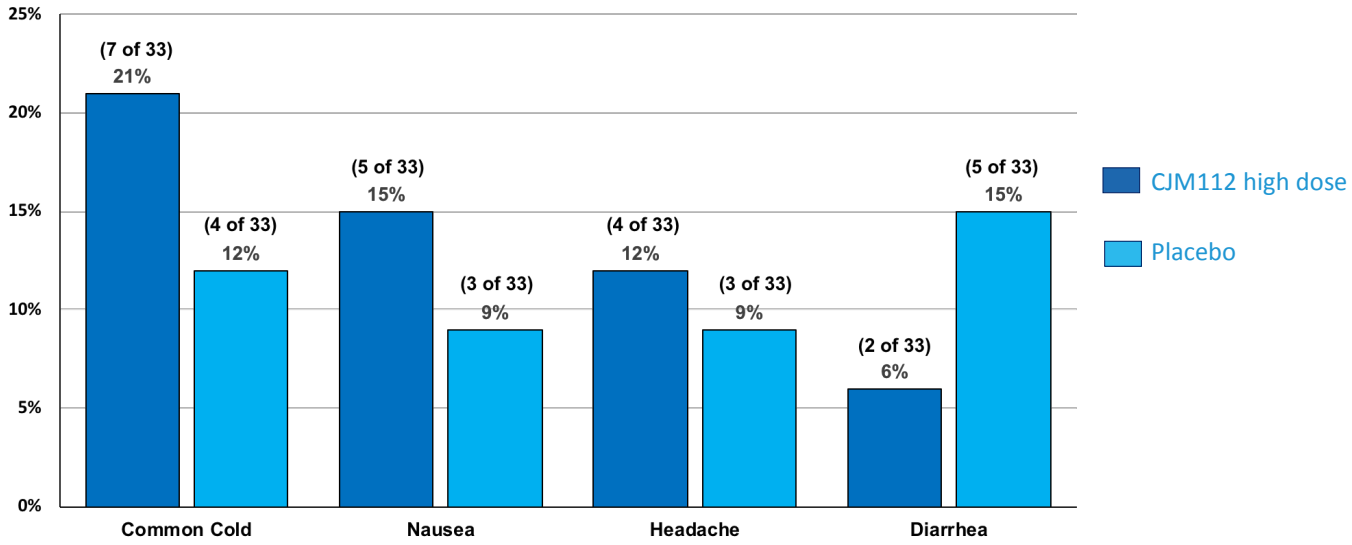
Some patients had medical problems or adverse events that were not serious.

This section shows the most common adverse events reported during the trial. Not all adverse events reported are listed here. This summary only lists the adverse events reported by at least 10% of all patients in each period. For example, if a group had 60 patients and 6 or more patients reported the same adverse event then it is reported here.

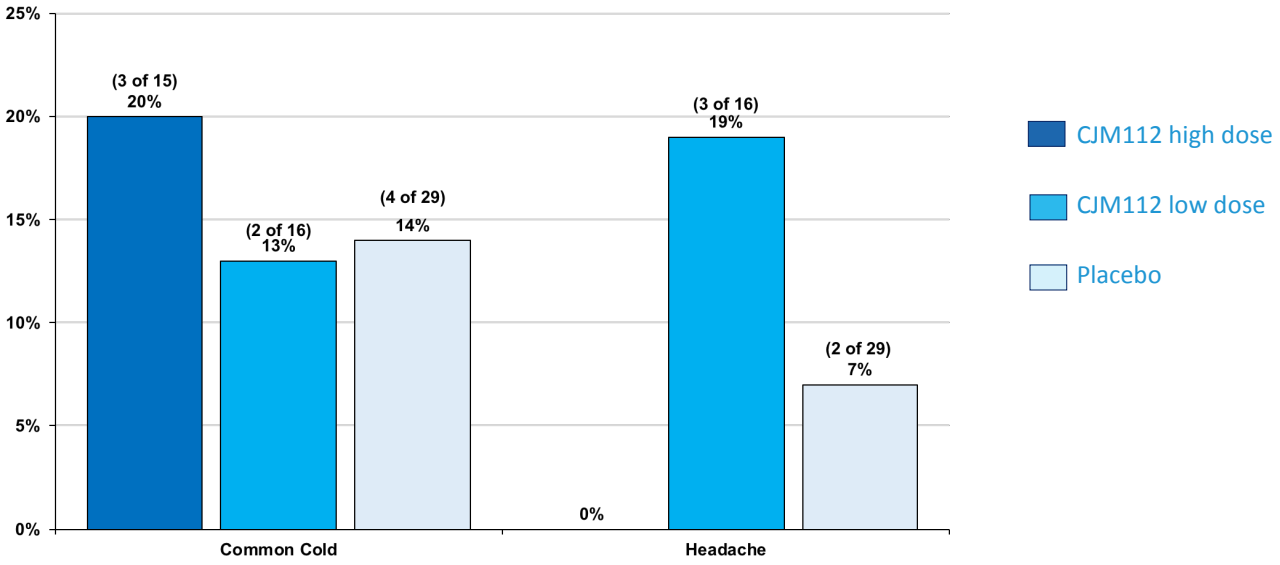
In Period 1, non-serious adverse events reported by at least 10% of patients were the common cold, nausea, headache, and diarrhea.

In Period 2, at least 10% of patients reported the common cold and headache.

Adverse events that were not serious and reported by at least 10 percent of patients during Period 1



Adverse events that were not serious and reported by at least 10 percent of patients during Period 2



For more information about the adverse events that patients reported in this clinical trial, visit novctrd.com. Use clinical trial number CCJM112X2202 to find the scientific summary.

How has this clinical trial helped?

This was the first clinical trial of CJM112 in patients with HS. The results of this trial helped researchers better understand how the body reacts to different doses of CJM112 and if the trial drug can help decrease HS symptoms.

This research may help future patients by helping doctors understand more about CJM112 as a possible treatment for HS.

The results presented here are for a single trial. No single clinical trial can give a complete picture of the benefits and risks of a trial drug. Researchers use the results of many clinical trials to help decide which treatments work best and are the safest. This summary shows only the main results from this trial. Other clinical trials may provide new information or different results.

Where can I learn more about this and future clinical trials?

If you were a patient in this clinical trial and have questions about the results, speak with the trial doctor or staff where you took part in this clinical trial.

This is a summary of the results for one clinical trial.

You can find detailed results and more information about this clinical trial on the Novartis Clinical Trial Results website:

1. Visit novctrd.com
2. Click on “Clinical trial results” at the top right of the page
3. Read and scroll down, then click “I accept” to agree to use the information and the website
4. Type CCJM112X2202 in the search box and click search

This clinical trial was registered on the following websites:

- ClinicalTrials.gov – https://clinicaltrials.gov – National Clinical Trial #NCT02421172
- European Union clinical register – https://www.clinicaltrialsregister.eu/ctr-search – EU Clinical Trial #2014-004731-39

If more clinical trials are planned, they will appear on the public websites listed above or at www.novartisclinicaltrials.com. When there, search for "CJM112."

Full trial title: A randomized, double-blind, placebo controlled, multiple dose study to evaluate the clinical efficacy, safety, tolerability, dose relation, pharmacokinetics and pharmacodynamics of CJM112 in moderate to severe chronic hidradenitis suppurativa patients.

Thank you!

Novartis would like to thank all of the trial participants that made this clinical trial possible. The participants from around the world have helped researchers answer important health questions and test new medical treatments. Many participants and many clinical trials are needed to advance medical science.

Health Literacy Media

911 Washington Ave., Suite 625,
St. Louis, Missouri, 63101
Email: info@healthliteracy.media

Phone: (314) 361-9400
www.healthliteracy.media

NOVARTIS

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

1-888-669-6682 (USA)
+41613241111 (EU)
www.novartisclinicaltrials.com