NOVARTIS

The effects and safety of CMK389 for people with eczema

Thank you!

Thank you to the participants who took part in the clinical trial for eczema. Every participant helped the researchers learn more about the trial drug **CMK389**.

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: CCMK389B12201
Drug studied: CMK389
Sponsor: Novartis

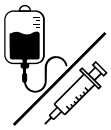
If you were a participant and have any questions about the results, please talk to the doctor or staff at the trial site.

This summary only shows the results of a single clinical trial. Other clinical trials may have different findings.

What was the main purpose of this trial?

The purpose of this trial was to learn about the effects and safety of CMK389 in people with moderate to severe eczema.

Eczema, also called atopic dermatitis, is a long-term skin condition that causes itchy and dry patches of skin. It can include a rash or raised bumps.



CMK389 is a trial drug designed to block a protein in the immune system that may play a role in eczema. Researchers think that blocking the protein may lessen people's eczema.

The main questions this trial was designed to answer:

- How many participants had clear or almost clear skin?
- What adverse events did the participants have during this trial?
  An adverse event is any sign or symptom that the participants have during a trial.

How long was this trial?

This trial began in April 2021 and ended in December 2022. Participants began the trial on different dates. It was planned for the participants to be in the trial for up to about 10 months. This included the time from starting treatment to the last time trial staff checked in with the participants.

Who was in this trial?

67 participants with moderate or severe eczema received a treatment in this trial – 45 men and 22 women. The participants were 19 to 63 years old. Their average age was 34.

66 participants reported their race as White, and one participant reported their race as Asian.

Every participant in this trial had eczema and:

- In the past, either used topical treatments that didn't work well to treat their eczema, or they couldn't use them
- Did not have certain other skin conditions

This trial took place in these countries:

- **Czech Republic |** 14 participants
- **France |** 4 participants
- **Germany |** 37 participants
- **Hungary |** 3 participants
- **Poland |** 7 participants
- **Spain |** 2 participants

What trial treatments did the participants receive?

Participants were randomly assigned to one of these treatment groups:

CMK389 – 10 milligrams for every kilogram of body weight (mg/kg) through a needle in a vein, which is called an intravenous (IV) infusion

CMK389 – 300 mg as an injection under the skin

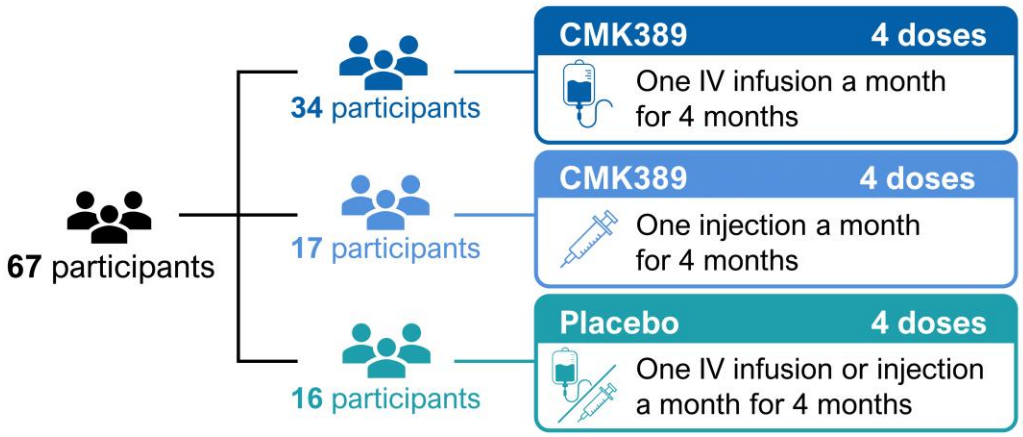
Placebo – looks like the trial drug but has no trial drug in it. Using a placebo helps researchers better understand the actual effects of a trial drug.

For this trial, participants received the placebo as an IV infusion or injection.

Participants received their assigned treatment one time a month for 4 months. A computer program was used to randomly assign the treatments. This helped make sure the researchers compared the results as fairly as possible.

The participants, some researchers, and most trial staff did not know what treatment each participant received. Some trials are done this way because knowing what treatment participants receive can influence the results. Not knowing what treatment participants receive helps make sure the results are looked at fairly.

The graphic below shows how many participants were assigned each treatment.



What were the main results of this trial?

How many participants had clear or almost clear skin?

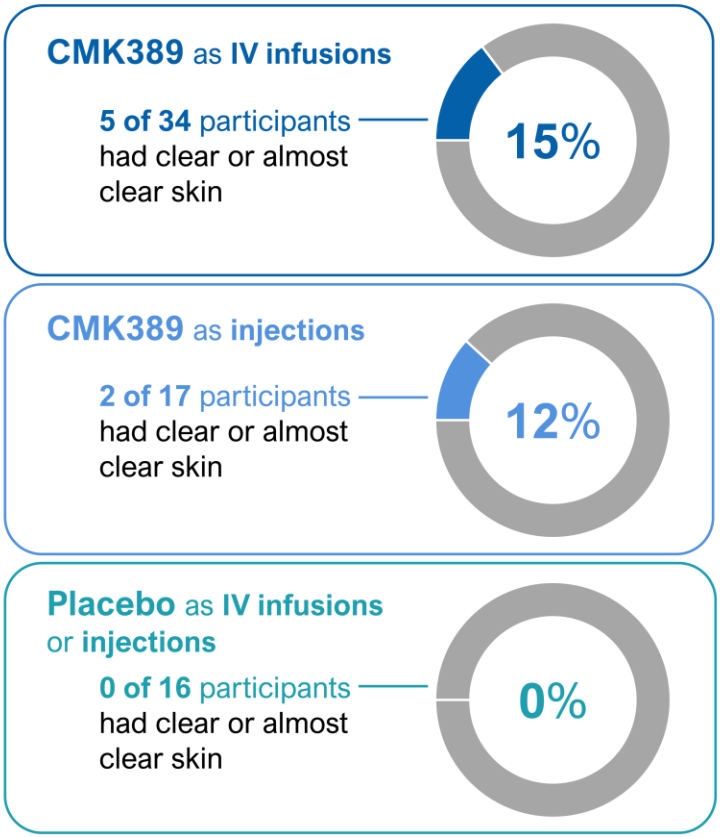
After 4 months of treatment, there was a slightly higher number of participants with clear or almost clear skin in the CMK389 IV infusion and injection groups compared to the placebo group.

To find this out, trial doctors rated how severe each participant's eczema was before and during the trial. They used a scale from 0 to 4, in which 0 means clear skin and 4 means severe eczema.

Before treatment, all participants had a score of 3 or 4 on this scale. After treatment, researchers counted how many participants had a score of 0 or 1, which is considered clear or almost clear skin.

Participants with clear or almost clear skin

The number and percent of participants in each treatment group with clear or almost clear skin (score of 0 or 1) after 4 months of treatment.



What adverse events did the participants have during this trial?

Trial doctors keep track of **all** adverse events that happen in trials, even if they think the adverse events are **not** related to the trial treatments.

Many trials are needed to know if a drug or treatment causes an adverse event.

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, the participant needs hospital care, or results in death

Adverse events **may** or **may not** be caused by treatments in the trial.

The adverse events in this section include any that happened during treatment and up to about 3 months after completing treatment. The researchers also kept track of any pregnancies that happened up to 6 months after completing treatment among women who could get pregnant.

The researchers concluded there were no new safety concerns for CMK389. A similar percent of participants had adverse events in each treatment group. One of the participants left the trial because of an adverse event.

How many participants had adverse events?

The table below shows the number of participants who had adverse events during the trial.

	CMK389 as **IV infusions** **34** participants	**CMK389** **as injections** **17** participants	**Placebo** as **IV infusions** or **injections** **16** participants
Participants who had at least 1 adverse event	**74%** 25 of 34	**65%** 11 of 17	**81%** 13 of 16
Participants who had at least 1 serious adverse event	**3%** 1 of 34	**6%** 1 of 17	**0%** 0 of 16
Participants who left the trial due to an adverse event	**0%** 0 of 34	**0%** 0 of 17	**6%** 1 of 16
Participants who died during the trial	**0%** 0 of 34	**0%** 0 of 17	**0%** 0 of 16

What were the serious adverse events?

The serious adverse events that happened in **2** participants who received **CMK389** were:

- **Heavy or long period** | heavy menstrual bleeding
- **Eczema that got worse** | dermatitis atopic

No other participants had serious adverse events, including no deaths.

What were the other adverse events?

The table below shows the adverse events that happened in **5 or more** participants. Additional adverse events happened in fewer participants.

	CMK389 as **IV infusions** **34** participants	**CMK389** as **injections** **17** participants	**Placebo** as **IV infusions** or **injections** **16** participants
COVID-19	**29%** 10 of 34	**29%** 5 of 17	**25%** 4 of 16
Common Cold Nasopharyngitis	**21%** 7 of 34	**24%** 4 of 17	**13%** 2 of 16
Eczema that got worse Dermatitis Atopic	**6%** 2 of 34	**12%** 2 of 17	**25%** 4 of 16
Frequent, loose, or watery stools Diarrhea	**9%** 3 of 34	**12%** 2 of 17	**0%** 0 of 16
Headache	**9%** 3 of 34	**6%** 1 of 17	**6%** 1 of 16

What was learned from this trial?

This trial helped researchers learn about the effects and safety of CMK389 in people with moderate to severe eczema.

After 4 months, the researchers found the percent of participants with clear or almost clear skin was:

- 15% of participants who received CMK389 as IV infusions
- 12% of participants who received CMK389 as injections
- 0% of participants who received placebo

The researchers found no new safety concerns for CMK389 in this trial.

These are the results of a single trial. This was one of many trials a drug may go through. This type of trial helped researchers learn about the safety of a trial drug in a small number of participants.

Where can I learn more about this and future trials?

To learn more about this trial, go to any of these websites:

- **novctrd.com** – search using the study number **CCMK389B12201**
- **clinicaltrials.gov** – search using the number **NCT04836858**
- **clinicaltrialsregister.eu/ctr-search** – search using the number **2020-003406-31**

When this summary was written, the sponsor did not have other trials planned for CMK389 in people with eczema.

Full trial title:

A randomized, subject and investigator blinded, placebo-controlled multicenter study to assess the efficacy and safety of CMK389 in patients with moderate to severe atopic dermatitis

? If you participated in the trial and have **questions** about the results, please speak with the trial doctors or staff at your trial site. Always talk to a doctor before making any changes to your health care.

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)

+41-61-324 1111 (EU)

www.novartisclinicaltrials.com