

The effects and safety of LYS006 for people with inflammatory acne



Thank you!

Thank you to the participants who took part in the clinical trial for inflammatory acne. Every participant helped the researchers learn more about **LYS006**.

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: CLYS006X2201

Drug studied: LYS006

Sponsor: Novartis

What was the main purpose of this trial?

The purpose of this trial was to learn about the effects and safety of LYS006 for people with inflammatory acne. To find this out, researchers compared the effects of LYS006 to a placebo.



Inflammatory acne is a skin condition that causes red and swollen pimples that are often painful and can damage the skin. Researchers think this acne may happen because the immune system is overactive and reacts to clogged skin pores. This can cause inflammation in the skin.

Inflammation is a part of the immune system's response to infection. Inflammation can cause swelling, redness, and pain. When related to acne, it can also create permanent scars.



LYS006 is a trial drug designed to block a protein in the immune system that may have a role in inflammatory acne.

A **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.

The main questions this trial was designed to answer:

- Did participants have fewer pimples on their faces after taking LYS006?
- What medical problems did the participants have during this trial?

Keeping track of the medical problems helped to learn about the safety of LYS006.



Main results: Overall, LYS006 did not lower the number of pimples on participants' faces. After 12 weeks of treatment, participants who took LYS006 had a similar number of pimples compared to participants who took a placebo.

The researchers concluded there were no new safety concerns for LYS006 in this trial.

How long was this trial?



The trial began in September 2018 and ended in March 2022. It was planned for the participants to be in the trial for about 5 months.

Who was in this trial?



66 participants were in this trial – 20 men and 46 women. The participants were 18 to 42 years old. Their average age was 24.

Participants reported their race as:

- Asian – 3 participants
- Black or African American – 9 participants
- White – 45 participants
- Other – 9 participants

Every participant in this trial had moderate to severe inflammatory acne and:

- Had 20 to 100 pimples on their face when the trial first started
- Did not respond well or could not use topical acne treatments, like creams
- Was in good overall health



This trial took place in the Czech Republic, France, Germany, Hungary, Netherlands, and the United States.

Visit novctrd.com for more information about:

- Who could and could not be in this trial
- Reasons why participants did not complete the trial

Use trial number **CLYS006X2201** to find the scientific summary.

What trial treatments did the participants take?

Participants were randomly assigned to one of these treatment groups:



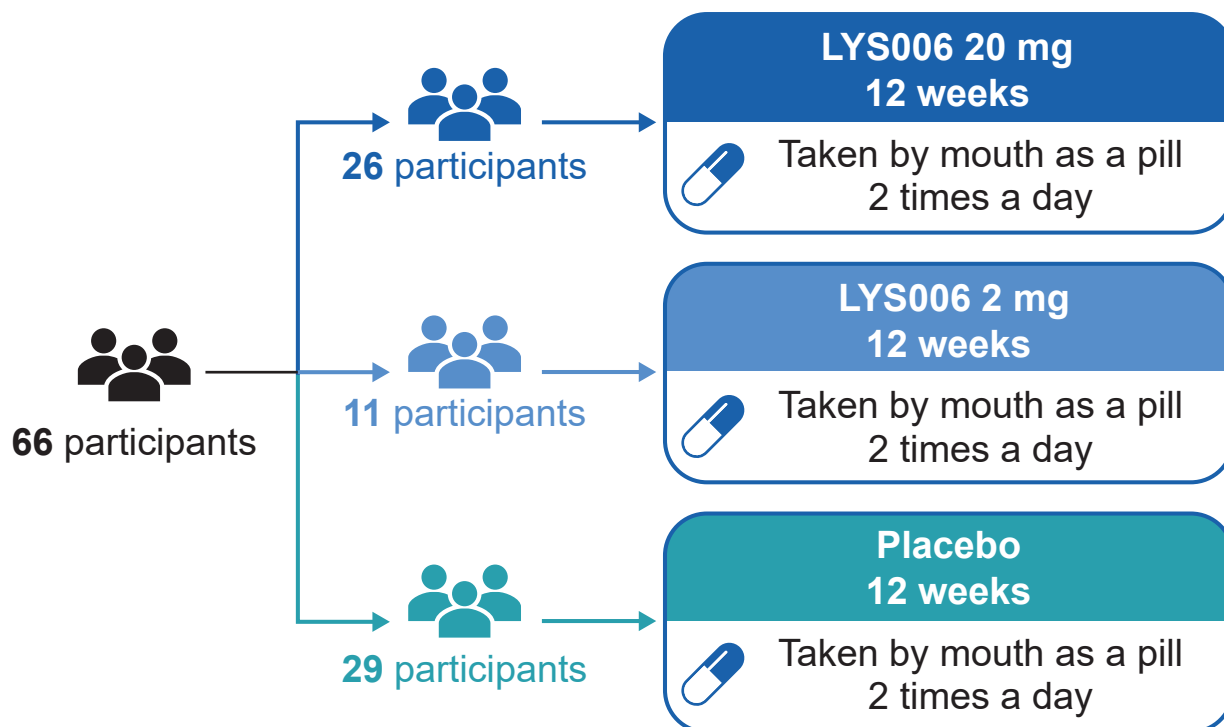
- **High dose of LYS006** – 20 milligrams (mg) 2 times a day
- **Low dose of LYS006** – 2 mg 2 times a day
- **Placebo** – 2 times a day

The participants took their assigned treatment by mouth as pills.

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, sponsor staff, and trial staff did not know what treatment each participant took during the trial. Some trials are done this way because knowing what treatment participants take can influence the results. Not knowing what treatment participants take helps make sure the results are looked at fairly.

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



What were the main results of this trial?



This is a summary of the overall results of this trial. Individual results from each participant may be different and are not included in this summary.

Researchers need many trials to learn if a drug or other treatment is safe and works well. Other trials may provide new information or different results.

Always talk to a doctor before making any changes to your health care.

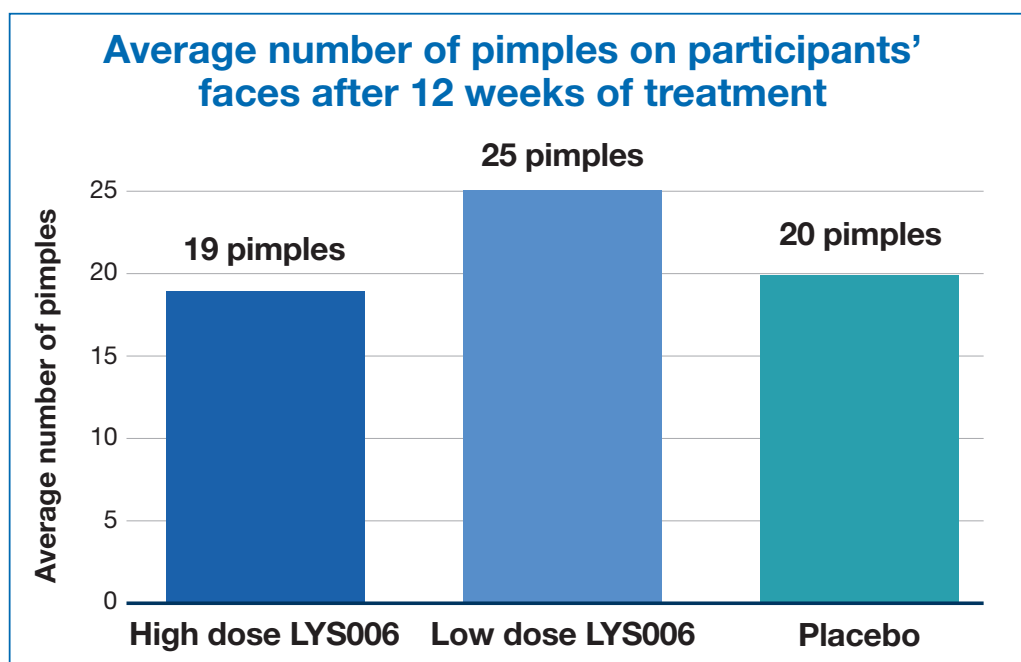
Did participants have fewer pimples on their faces after taking LYS006?



No. After 12 weeks of treatment, participants who took LYS006 had about the same number of pimples on their faces compared to those who took the placebo. The researchers concluded there was no meaningful difference between the LYS006 and placebo groups.

To find this out, trial doctors counted the number of pimples on the participants' faces after 12 weeks of treatment. Then, the researchers compared the average number of pimples for participants who took either dose of LYS006 to those who took the placebo.

After 12 weeks, the researchers found that participants who took LYS006 had a similar number of pimples compared to those who took the placebo.



What medical problems did the participants have during this trial?

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

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.

The adverse events in this section include any that happened during treatment and up to 1 month after completing treatment.

An adverse event is:

- Any **unwanted 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.



About half of the participants (34 of 66 participants) had adverse events. None of the participants had adverse events that were considered serious. The most common type of adverse event was a common cold. One participant in each group left the trial due to adverse events.

The researchers concluded there were no new safety concerns for LYS006 in this trial.

What serious adverse events did the participants have?

None of the participants had serious adverse events, including no deaths.

What other adverse events did the participants have?

High dose of LYS006: 10 of 26 or 39% of participants had an adverse event.

Low dose of LYS006: 8 of 11 or 73% of participants had an adverse event.

Placebo: 16 of 29 or 55% of participants had an adverse event.

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

	High dose of LYS006 26 participants	Low dose of LYS006 11 participants	Placebo 29 participants
Common cold Nasopharyngitis	12% 3 of 26	27% 3 of 11	10% 3 of 29
Higher levels of a protein in the blood, which is usually a sign of muscle injury Blood creatine phosphokinase increased	8% 2 of 26	9% 1 of 11	10% 3 of 29
Crystals in the urine, which happens when there are too many minerals and not enough liquid Crystal urine present	8% 2 of 26	0% 0 of 11	14% 4 of 29
Headache	0% 0 of 26	18% 2 of 11	10% 3 of 29

What was learned from this trial?

The trial helped researchers learn about the effects and safety of LYS006 in people with inflammatory acne.

The researchers concluded that LYS006 did not lower the number of pimples on participants’ faces. The researchers found no new safety concerns for LYS006 in this trial.

These are the results of a single trial. Other trials may have different results. This was one of many trials a drug goes 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 trial and future trials?

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

- novctrd.com – search using the trial number **CLYS006X2201**
- clinicaltrials.gov – search using the number **NCT03497897**
- clinicaltrialsregister.eu/ctr-search/ctr-search – search using the number **2017-003191-30**

If more trials are planned, they will appear on the public websites above. When there, search for **LYS006**, **inflammatory acne**, or **inflammatory skin diseases**.

Full clinical trial title: A randomized, subject and investigator blinded, placebo-controlled, multi-center study in parallel groups to assess the efficacy and safety of LYS006 in subjects with moderate to severe inflammatory acne.

? If you participated in the trial and have **questions** about the results, please speak with the trial doctors or staff at your trial site.



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

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