NOVARTIS

The effects and safety of LYS006 for people with ulcerative colitis

Thank you!

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

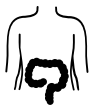
Trial number: CLYS006X2202
Drug studied: LYS006
Sponsor: Novartis

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 main purpose of this trial was to learn about the effects and safety of LYS006 in people with mild to moderate ulcerative colitis.



Ulcerative colitis, also called UC, is a long-term disease where parts of the digestive system become inflamed. This can lead to tiny open sores, called ulcers.

Symptoms of mild to moderate UC include belly cramps and pain, many bowel movements a day, and blood in the stool. UC symptoms often come and go, with periods of symptoms and periods without symptoms called **remission**.

Researchers don't know the exact cause of UC, but inflammation from an overactive immune system may play a role. **Inflammation** is the immune system's response to protect the body from infection, but too much inflammation can damage the body.

LYS006 is a trial drug that blocks a certain protein that plays a role in inflammation. Researchers think blocking this protein may lower inflammation in the colon.

The main questions this trial was designed to answer:

- What percent of participants had UC remission after trial treatment?
- What adverse events did the participants have during this trial?
  An adverse event is any sign or symptom that participants have during a trial.

How long was this trial?

This trial began in February 2020. Participants began the clinical trial on different dates. It was planned for the participants to be in the trial for up to about 4 months. This included the time from starting treatment to the last time trial staff checked in with the participants.

In November 2022, the sponsor decided to end the trial early. They had enough information from the trial to decide whether research of LYS006 in UC should continue. The trial did not end due to safety concerns.

Who was in this trial?

23 participants with mild to moderate UC were in this trial – 13 women and 10 men. The participants were 19 to 64 years old. Their average age was 41.

All 23 participants reported their race as White.

Every participant in this trial:

- Did not respond well or could not take standard medicines for UC
- Did not have certain other digestive diseases, such as Crohn's disease

This trial took place in these countries:

- **Poland | 7** participants
- **Czech Republic | 6** participants
- **Russia | 4** participants
- **Slovakia | 3** participants
- **Germany | 2** participants
- **Bulgaria | 1** participants

What trial treatments did the participants take?

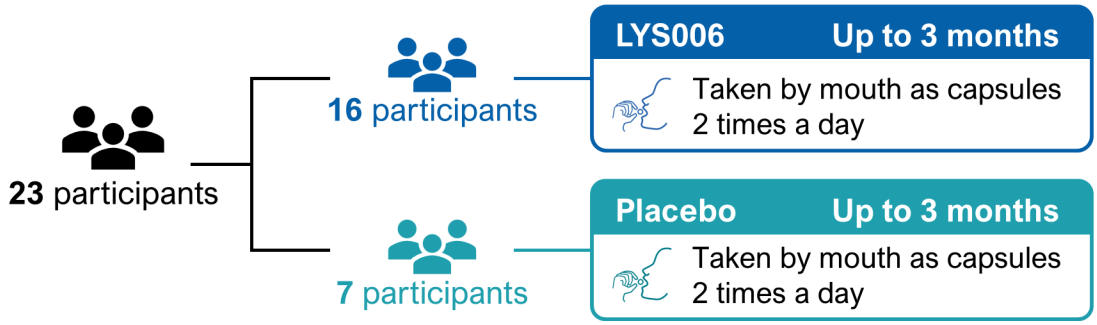
Participants were randomly assigned to one of these treatments:

- **LYS006** – 20 milligrams (mg)
- **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 participants took their assigned treatment by mouth as capsules 2 times a day. 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, researchers, and trial staff did not know what treatment each participant took. 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 long and how often participants took each treatment.



What were the main results of this trial?

What percent of participants had UC remission after trial treatment?

The percent of participants with UC remission after treatment was about the same in the LYS006 and placebo groups.

The researchers concluded there was no meaningful difference between LYS006 and the placebo.

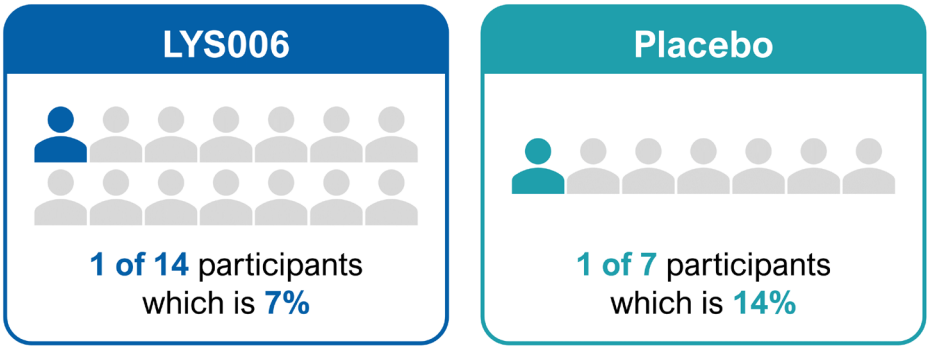
To find this out, the researchers compared participants' Mayo scores before and after treatment. The **Mayo score** is a tool used by doctors to measure UC severity. The Mayo score ranges from 0 to 12. A **lower score** means **less severe** UC.

The researchers compared how many participants in each treatment group had their Mayo score go down to 2 or less. This was considered **UC remission** in the trial.

What is the Mayo score based on?
The Mayo score is based on:

- How often the participant passed stool
- How often the participant had rectal bleeding
- Images of the participant's digestive tract
- A doctor's review of how severe the participant's UC was

Percent of participants with UC remission after treatment



This graphic only includes participants who completed their treatment as planned.

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 30 days after completing treatment.

The researchers concluded there were no new safety concerns for LYS006 in this trial. The most common adverse event was UC that got worse. 2 of the participants stopped treatment 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.

	LYS006 16 participants	Placebo 7 participants
Participants who had at least 1 adverse event	44% 7 of 16	71% 5 of 7
Participants who had at least 1 serious adverse event	0% 0 of 16	0% 0 of 7
Participants who stopped taking the trial drug due to an adverse event	13% 2 of 16	0% 0 of 7
Participants who died during the trial	0% 0 of 16	0% 0 of 7

What were the serious adverse events?

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

What were the other adverse events?

The table below shows the adverse events that happened to **2 or more participants**. Additional adverse events happened to fewer participants.

	LYS006 16 participants	Placebo 7 participants
UC that got worse Colitis ulcerative	19% 3 of 16	14% 1 of 7

What was learned from this trial?

This trial helped researchers learn about the effects and safety of LYS006 in people with mild to moderate UC.

The researchers concluded that LYS006 did not have a meaningful effect on UC remission. The researchers found no new safety concerns for LYS006 in this trial.

These are the results of a single trial. 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 and future trials?

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

- **novctrd.com** – search using the study number **CLYS006X2202**
- **clinicaltrials.gov** – search using the number **NCT04074590**
- **clinicaltrialsregister.eu/ctr-search** – search using the number **2019-003113-34**

At this time, no other studies are planned for LYS006 in UC.

Full trial title: A randomized, multi-center, subject and investigator-blinded, placebo-controlled, parallel-group study to assess the efficacy safety and tolerability of LYS006 in patients with mild to moderate ulcerative colitis

? If you participated in the trial and have **questions** about the results, please speak with the trial doctor 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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