NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about the safety of LOU064 and how the body processes it in people with and without liver disease

Thank you!

Thank you to the participants who took part in the clinical trial. Every participant helped the researchers learn more about the trial drug **LOU064**, also called remibrutinib.

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: CLOU064A2101

Novartis drug studied: **LOU064**, also called remibrutinib

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 results.

What was the main purpose of this trial?

The purpose of this trial was to help researchers learn if liver disease changes how the body processes the trial drug **LOU064**. The researchers also wanted to learn about the safety of **LOU064** in people with and without liver disease.

Liver disease is a group of conditions that cause liver damage and scarring. Because the liver helps to process certain drugs, liver disease can change how the body processes drugs like **LOU064**.

LOU064 is a trial drug designed to treat certain autoimmune diseases. This trial did not look at the effects of **LOU064** on autoimmune diseases.

Why the researchers did this trial:

Many health authorities require a trial like this before they can approve certain types of drugs. Results from this type of trial can also inform how doctors may prescribe the drug for people with liver disease.

The trial's purpose was to answer these main questions:

- Did liver disease change how the body processes LOU064?
- What medical problems, also called adverse events, happened during this trial?
  - ↳ An **adverse event** is any sign or symptom that participants have during a trial. Adverse events **may** or **may not** be caused by treatments in the trial.

How long was this trial?

The trial began in October 2022 and ended in December 2023.

Who was in this trial?

38 participants received treatment in this trial – 23 men and 15 women. Participants' ages ranged from 24 to 67 years. Their average age was 52 years.

The number of participants by race is shown below.

Race

38	White

Out of the 38 participants:

- 8 participants had **mild liver disease**
- 8 participants had **moderate liver disease**
- 7 participants had **severe liver disease**
- 15 participants were **healthy** and did not have liver disease

Researchers included healthy participants so they could compare their trial results to those that had liver disease.

This trial took place in Hungary.

What treatments did the participants receive?

The treatment in this trial was:

LOU064, which participants took as a 25 milligram (mg) capsule by mouth for 3 days. Participants first took **LOU064** for 2 times a day for 2 days and then 1 time a day for 1 day.

The participants took **LOU064** while fasting, which meant they did not eat for up to 10 hours before taking it.

The participants, researchers, and trial staff knew what treatment the participants took. Participants could continue taking certain prescribed medicine for liver disease during this trial.

What happened during this trial?

Before treatment

About 1 month

Trial staff checked to make sure the participants could be in this trial.

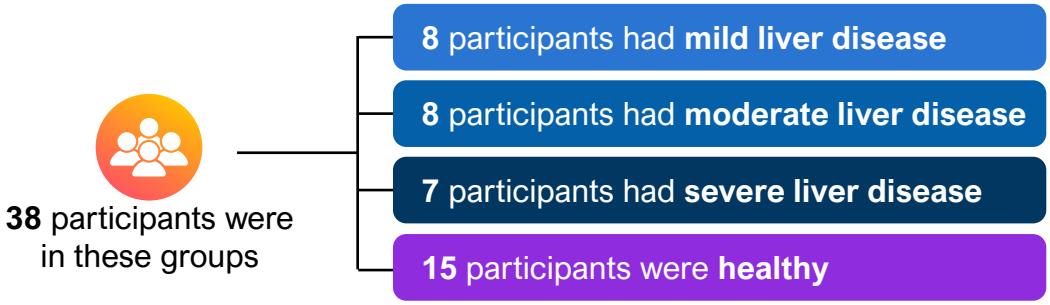
During treatment

About 8 days

Participants took **LOU064** for 3 days. Each participant stayed at the trial site for about 8 days after starting treatment.

Trial staff took blood samples to measure the amount of **LOU064** in the participants' blood many times during their trial stay.

The graphic below shows how many participants were in each group.



After treatment

About 1 month

Trial staff checked participants for any medical problems about 1 month after their last dose of trial treatment.

Trial staff checked the participants' general health throughout the trial.

What were the main results of this trial?

Did liver disease change how the body processes LOU064?

The researchers concluded that mild, moderate, and severe liver disease changed how the body processes **LOU064**.

To find this out, the trial staff took many blood samples from each participant after they received **LOU064**. The researchers measured the participants' blood samples for the:

- Total amount of **LOU064**
- Peak level of **LOU064**
- Time it took **LOU064** to reach peak level
- Length of time **LOU064** stayed in the blood

Then, the researchers compared these measures between **participants with liver disease** and **healthy participants**. Below is a summary of what researchers found:

The **total amount** of **LOU064** was:

Higher in participants with mild, moderate, or severe liver disease

The **peak level** of **LOU064** was:

Higher in participants with mild, moderate, or severe liver disease

The time it took **LOU064** to **reach the peak level** was:

About the same for participants with mild or moderate liver disease

Slightly shorter for participants with severe liver disease

The length of time **LOU064** **stayed in the blood** was:

Longer for participants with mild, moderate, or severe liver disease

What medical problems, also called adverse events, happened during this trial?

Trial doctors keep track of all medical problems, also called **adverse events**, that happen in trials. They track adverse events 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.

This section is a summary of the adverse events that happened from the first dose of trial treatment until about 1 month after the last dose.

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.

Some of the participants (10 of 38 participants) had adverse events. No participants had adverse events that were considered serious. No participants died. No participants left the trial due to an adverse event. The researchers concluded there were no safety concerns for **LOU064** in this trial.

How many participants had adverse events?

	Participants with mild liver disease 8 participants	Participants with moderate liver disease 8 participants	Participants with severe liver disease 7 participants	Healthy participants 15 participants
Had at least 1 **serious adverse event**	0 of 8 0%	0 of 8 0%	0 of 7 0%	0 of 15 0%
Had at least 1 **other adverse event**	4 of 8 50%	2 of 8 25%	0 of 7 0%	4 of 15 27%
Left the trial due to an adverse event	0 of 8 0%	0 of 8 0%	0 of 7 0%	0 of 15 0%
Died	0 of 8 0%	0 of 8 0%	0 of 7 0%	0 of 15 0%

What serious adverse events did the participants have?

No participants had serious adverse events. No participants died.

What other adverse events did the participants have?

10 participants had other adverse events.

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

	Participants with mild liver disease 8 participants	Participants with moderate liver disease 8 participants	Participants with severe liver disease 7 participants	Healthy participants 15 participants
Headache	1 of 8 13%	1 of 8 13%	0 of 7 0%	1 of 15 7%
Feeling sick to the stomach Nausea	1 of 8 13%	0 of 8 0%	0 of 7 0%	1 of 15 7%
Throwing up Vomiting	1 of 8 13%	0 of 8 0%	0 of 7 0%	1 of 15 7%

What was learned from this trial?

Researchers learned about how the body processes **LOU064** and its safety in people with and without liver disease.

The researchers concluded that:

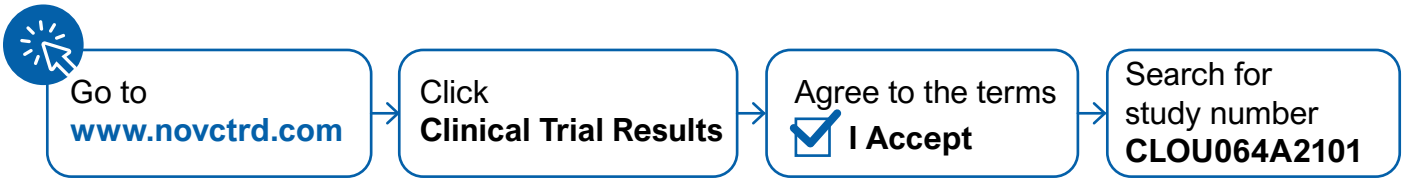
- Mild, moderate, and severe liver disease changed how the body processes **LOU064**
- There were no safety concerns for **LOU064** in this trial

When this summary was written, the sponsor had plans for future trials with **LOU064**.

Where can I learn more about this trial?

More information about the results and adverse events in this trial can be found in the scientific summary of the results available on the Novartis Clinical Trial Results website **www.novctrd.com**

Follow these steps to find the scientific summary:



For more information about this trial, go to this website:

- **clinicaltrials.gov** – search using the number **NCT05753592**

Other trials of **LOU064** may appear on the public websites above. When there, search for **LOU064** or remibrutinib.

Full clinical trial title: A Phase 1, open-label, study to investigate the pharmacokinetics and safety of remibrutinib (LOU064) in participants with hepatic impairment compared to matched healthy participants with normal hepatic function

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