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 kidney disease

Thank you!

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

Novartis sponsored this trial. We believe 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: CLOU064A2105

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

Sponsor: Novartis

If you were a participant and have any questions about the results, please talk to your 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 kidney 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 kidney disease.



Kidney disease is a long-term condition in which the kidneys are damaged.

This trial looked at kidney disease that caused severe damage to the kidneys. Because the kidneys help to process certain drugs and remove them from the body in urine, kidney disease can change how the body processes drugs like **LOU064**.



LOU064, also called **remibrutinib**, is a trial drug created to treat certain autoimmune diseases, such as lupus. An autoimmune disease is caused by the immune system attacking healthy cells by mistake. 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 kidney disease.



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

- Did kidney disease change how the body processes LOU064?
- What medical problems, also called adverse events, happened during this trial?

  ↳ **Adverse events** reported are any sign or symptom that participants had during this trial. Adverse events **may** or **may not** be caused by treatments in this trial.

How long was this trial?



The trial began in July 2025 and ended in October 2025. The participants started the trial on different dates.

At the end of this trial, Novartis created a report of the trial results. This summary is based on that report.

Who was in this trial?

16 participants received treatment in this trial – 14 males and 2 females. Participants' ages ranged from 34 to 75 years. Their average age was 58 years.

The table below shows the number of participants by race.

Race	
4 Black or African American	12 White

Out of the 16 participants:

- 8 participants had severe kidney disease, which meant they had an eGFR blood test result of less than 30 and were **not on dialysis**
- 8 participants were considered healthy and did not have kidney disease

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

This trial took place in the United States.

What treatment did the participants receive?

The treatment in this trial was:

LOU064 – 100 milligrams (mg) taken by mouth as tablets for 3 days. Participants first took **LOU064** 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 and up to 2 hours after taking it for the first 2 days. On day 3, they did not eat for up to 10 hours before and 4 hours after taking **LOU064**.

The participants, researchers, and trial staff knew that all participants took **LOU064**. Participants with kidney disease could continue taking certain medicines for their disease during this trial.

What happened during this trial?

Before treatment

About 1 month

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

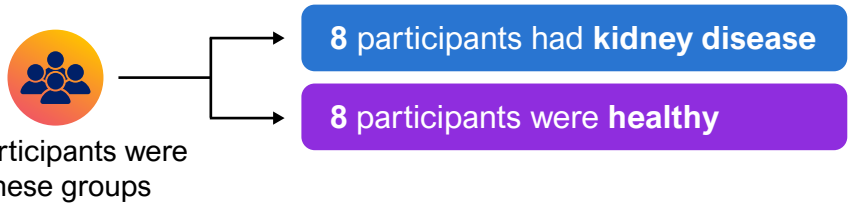
During treatment

About 8 days

Participants took **LOU064** for 3 days. Each participant stayed at the trial site for about 8 days after they started taking **LOU064**.

Trial staff took blood and urine samples many times during the participants' stay at the trial site. They used the samples to measure the amount of **LOU064** in the body.

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



After treatment

About 1 month

Trial staff checked participants for any medical problems for up to 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 kidney disease change how the body processes LOU064?

The researchers concluded that kidney disease may have changed how the body processes **LOU064**.

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

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

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

The **total amount** and **peak level** of **LOU064** in the blood was:

Higher in participants with kidney disease than healthy participants

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

About the same in participants with kidney disease and healthy participants

The **total amount** of **LOU064** in the urine was:

Lower in participants with kidney disease than healthy participants

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 do this even if they think the adverse events are not related to the trial treatments.

Researchers need results from many trials to decide if a drug or treatment causes an adverse event.

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

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, requires hospital care, or results in death

Treatments in the trial **may** or **may not** cause adverse events.



2 out of 16 participants had adverse events.

- No participants had serious adverse events
- No participants died

The researchers concluded there were no new safety concerns for **LOU064** in this trial.

What serious adverse events did the participants have?

No participants had serious adverse events.

What other (not including serious) adverse events did the participants have?

2 participants had other adverse events.

1 participant with kidney disease had:

- **Headache**

1 healthy participant had:

- **Blood in the urine** (hematuria)
- **Fever** (pyrexia)
- **Headache**
- **Possible sign of inflammation** (C-reactive protein increased)
- **Redness and swelling in the eyelid** (blepharitis)
- **Stuffy nose** (nasal congestion)

What was learned from this trial?

Researchers learned if kidney disease changes how the body processes the trial drug **LOU064**. The researchers also learned about the safety of **LOU064** in people with and without kidney disease.

The researchers concluded that:

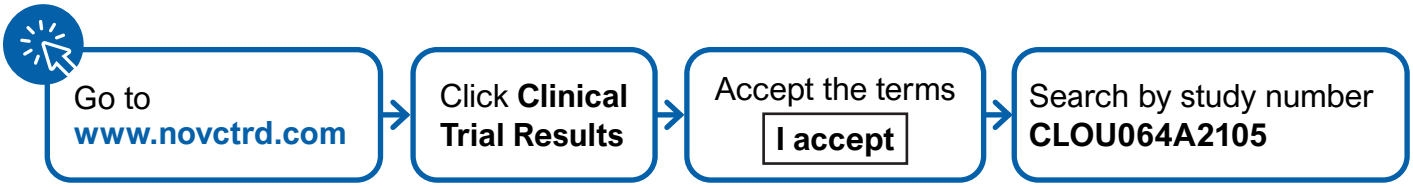
- Kidney disease may have changed how the body processes **LOU064**
- There were no safety concerns for **LOU064** in this trial

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

Where can I learn more about this trial?

To learn more about the results and adverse events in this trial, read the scientific summary of the results. It is 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 **NCT07032272**

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 severe renal impairment compared to matched healthy participants with normal renal function



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

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