

# The effects and safety of the trial drug LOU064 for people with poorly controlled asthma



## Thank you!

Thank you to the participants who took part in the clinical trial for **LOU064**, also called **remibrutinib**. Every participant helped the researchers learn more about how LOU064 works and its safety in people with asthma.

## What was the main purpose of this trial?

The main purpose of this trial was to learn if LOU064 changed how easily participants with poorly controlled asthma could breathe. The trial also learned more about the safety of LOU064.



**Poorly controlled asthma** is asthma that isn't well treated with commonly used asthma medicines.



**LOU064** is a trial drug designed to lower the activity of certain cells in the immune system. Researchers suspect that overactive immune cells may play a role in some types of asthma.

### The main questions this trial was designed to answer:

- Did LOU064 change how easily the participants could breathe?
  - What medical problems did the participants have during this trial?
- Keeping track of the medical problems helped to learn about the safety of LOU064.



**Main results:** The clinical trial team concluded that LOU064 did not meaningfully change how easily the participants could breathe. Because of this, the trial ended early. The most common medical problem was the common cold. The team found no safety concerns for LOU064.

## How long was this trial?

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The trial began in July 2019 and ended in April 2020. The participants could take part in the trial for about 5 months.



The sponsor decided to end the trial early. This was because early data from this trial showed that LOU064 did not meaningfully change the participants' breathing. The decision to end the trial was not related to safety.

## Who was in this trial?

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76 participants were in this trial – 50 women and 26 men. 22 participants did not complete this trial, mainly because the trial ended early. The participants were 29 to 70 years old. Their average age was 51.

Every participant in this trial had poorly controlled asthma and:

- Had not recently smoked or breathed in (inhaled) any substance other than asthma medicines
- Did not have any other lung-related disease, such as COPD (Chronic Obstructive Pulmonary Disease)
- Had no serious changes in their asthma symptoms during the 6 weeks before the trial
- Was in good overall health



This trial took place in Argentina, Germany, Poland, Russia, and the United States.

Visit [novctrd.com](https://novctrd.com) for more information about:

- Who could and could not be in this trial
- The participants in this trial, such as their age, gender, and race
- Reasons why the participants did not complete the trial

Use trial number **CLOU064D12201** to find the scientific summary.

## What trial treatments did the participants take?

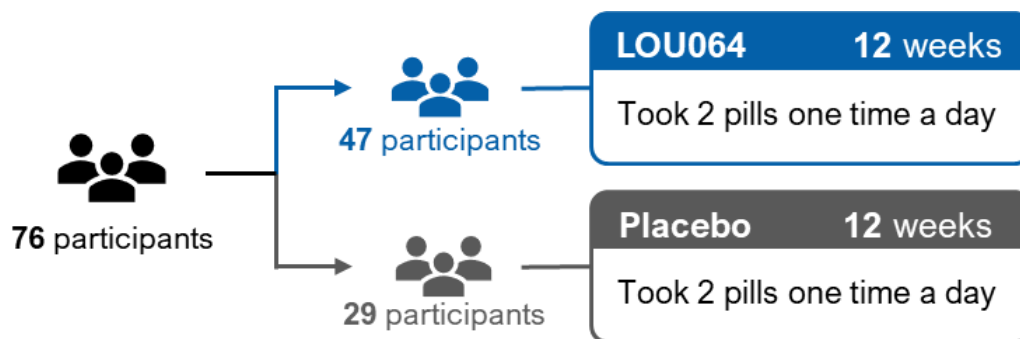
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A computer program was used to randomly assign each participant to one of the following:

- **LOU064** – 100 milligrams, taken by mouth as 2 pills one time a day
- **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.

Along with their trial treatment, each participant also used an inhaler to take 2 commonly used asthma medicines twice a day: a corticosteroid and a long-acting beta-2 agonist. Each participant was also given a rescue inhaler to use as needed. The graphic on the next page shows the number of participants assigned each trial treatment.



The participants 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.

## 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 LOU064 change how easily the participants could breathe?



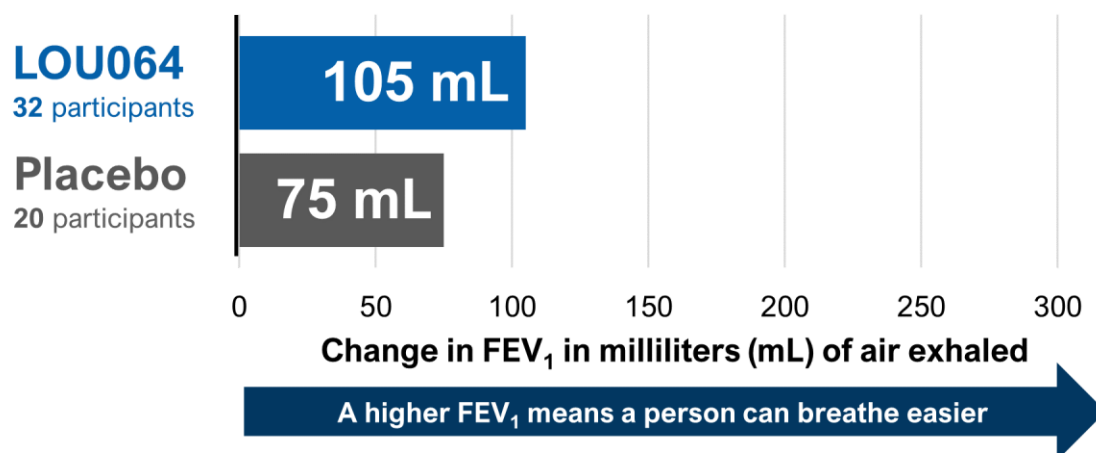
On average, the participants who took LOU064 could breathe slightly easier compared to those who took the placebo. The clinical trial team concluded this difference was too small to have a meaningful effect on breathing.

To find this out, the clinical trial team used a measure called Forced Expiratory Volume during 1 second, also called **FEV<sub>1</sub>**. This is how many milliliters (mL) of air a person can blow out (exhale) with force in 1 second. Asthma narrows the airways in the lungs and lowers the amount of air a person can exhale. A higher FEV<sub>1</sub> means that a person can breathe easier.

Before the trial started, the team decided how much the participants' FEV<sub>1</sub> would need to change to show that LOU064 had a meaningful effect compared to placebo. The team decided a change of 130 mL more would be a meaningful effect.

After 12 weeks of treatment, the average change in FEV<sub>1</sub> for the participants who took LOU064 was only about 30 mL more than those who took the placebo. The team concluded this difference was too small to have a meaningful effect on breathing.

## Change in FEV<sub>1</sub> from before treatment to after 12 weeks of treatment



**Note:** This graph only includes results from participants who completed all 12 weeks of treatment.

## What medical problems did the participants have during this trial?

Medical problems that happen during trials are called “adverse events”. Trial doctors looked for any adverse events during the visits to the trial site. The participants also reported adverse events.

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

### 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

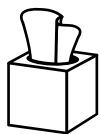
Adverse events **may or may not be caused** by treatments in the trial.



No serious adverse events were reported, including deaths. About half of the participants reported adverse events that were not serious. The participants who took LOU064 had a similar number of adverse events compared to those who took the placebo.

The most common adverse event was the common cold. 2 participants who took the placebo left this trial because of adverse events.

The adverse events that happened in **3 or more participants** were:



**Common Cold**  
Nasopharyngitis



**Infection in the nose, throat, and airways**  
Upper respiratory tract infection

A similar number of participants in both treatment groups reported these adverse events. Other adverse events were reported by fewer participants.

## What other results were learned?

The clinical trial team also looked at other measures of the participants' asthma symptoms:

- The trial staff asked the participants a set of questions about their symptoms during visits to the trial site
- Each day and night during treatment, the participants:
  - Reported how well they could breathe by using a peak flow meter, which is a handheld device that measures how fast they could exhale air
  - Rated their asthma symptoms
  - Reported how often they used their rescue inhaler

The team found that, on average, LOU064 did not have a meaningful effect on these measures compared to the placebo.

## What was learned from this trial?

This was the first trial to learn about the effects and safety of LOU064 in a small number of participants with poorly controlled asthma. The clinical trial team concluded that LOU064 did not meaningfully change the participants' breathing. Because of this, the trial ended early. They found no safety concerns for LOU064.

This was one of many trials a drug must go through before it can be approved for doctors to prescribe. LOU064 is no longer being studied as a possible treatment for poorly controlled asthma. If more trials are planned for other health conditions, they will appear on the public websites below. When there, search for **LOU064**, **remibrutinib**, or **asthma**.

## Where can I learn more about this trial?

For more information about this trial, search for **CLOU064D12201** at any of these websites:

- [novctrd.com](https://novctrd.com) Novartis clinical trial results
- [clinicaltrials.gov](https://clinicaltrials.gov) ClinicalTrials.gov
- [clinicaltrialsregister.eu/ctr-search](https://clinicaltrialsregister.eu/ctr-search) European Union Clinical Trials Register



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



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