NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about how the body processes JDQ443 and its safety 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 **JDQ443**, also called opnurasib.

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: CJDQ443B12103

Novartis drug studied: **JDQ443**, also called opnurasib

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 **JDQ443**. The researchers also wanted to learn about the safety of **JDQ443** 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 **JDQ443**.

JDQ443 is a trial drug designed to treat certain types of cancer. This trial did not look at the effects of **JDQ443** on cancer.

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 JDQ443?
- 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 May 2022 and ended in April 2024.

The sponsor decided to end the trial early and stop research on **JDQ443**. This was a business decision and not related to the safety of **JDQ443**.

Who was in this trial?

33 participants received treatment in this trial – 15 men and 18 women. Participants' ages ranged from 40 to 72 years. Their average age was 60 years.

The number of participants by race is shown below.

Race

1 Asian	3 Black or African American	29 White

Out of the 33 participants:

- 8 participants had **mild liver disease**
- 8 participants had **moderate liver disease**
- 5 participants had **severe liver disease**
- 12 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 the United States.

What treatment did the participants receive?

The treatment in this trial was:

JDQ443, 200 milligrams (mg), which participants took as tablets one time by mouth.

The participants, researchers, and trial staff knew what treatment the participants took. All participants took **JDQ443**.

Participants with liver disease could continue taking certain medicines for their condition during this trial.

What happened during this trial?

Before treatment — About 1 month

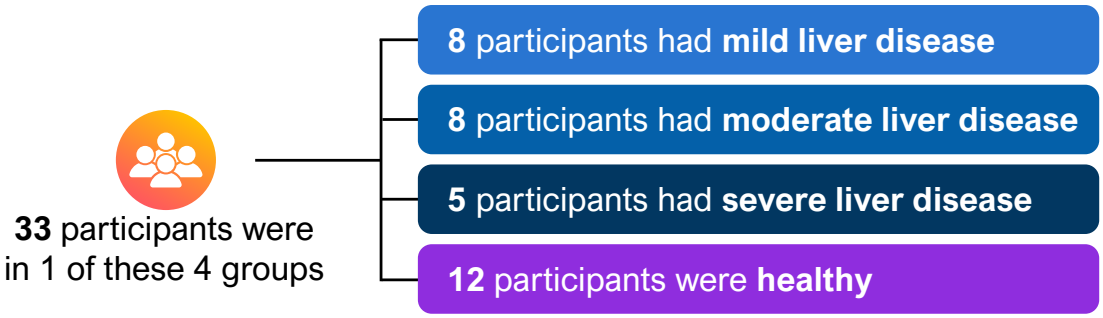
Trial staff checked the participants to make sure they could be in this trial.

During treatment — About 1 week

Every participant took **JDQ443** one time. Participants stayed at the trial site for 4 days.

Trial staff took blood samples to measure the amount of **JDQ443** in the participants' blood many times during their trial stay.

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



Participants with mild and moderate liver disease and some healthy participants took **JDQ443** first. The researchers then checked how the body processed **JDQ443** and for any safety concerns.

After researchers found no meaningful changes or safety concerns, those with severe liver disease and the remaining healthy participants took **JDQ443**.

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 JDQ443?

The researchers concluded that mild and moderate liver disease changed how the body processes **JDQ443**. Because the trial ended early, there were too few participants with severe liver disease to conclude if it changed how the body processes **JDQ443**.

To find this out, the trial staff took many blood samples from each participant after they took **JDQ443**. The researchers measured the participants' blood samples for the:

- Total amount of **JDQ443**
- Peak level of **JDQ443**
- Time it took **JDQ443** to reach peak level
- Length of time **JDQ443** stayed in the blood

Then, the researchers compared these measures between **participants with liver disease** and **healthy participants**. Because the trial ended early, there were too few participants with severe liver disease to conclude if it changed how the body processes **JDQ443**. Below is a summary of what researchers found.

The **total amount** of **JDQ443** was:

Slightly lower in participants with mild liver disease

Lower in participants with moderate liver disease

The **peak level** of **JDQ443** was:

Slightly lower in participants with mild liver disease

Lower in participants with moderate liver disease

The time it took **JDQ443** to **reach the peak level** was:

Slightly shorter for participants with mild liver disease

Slightly longer for participants with moderate liver disease

The length of time **JDQ443** **stayed in the blood** was:

About the same for participants with mild and moderate 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 start of treatment until about 1 month after 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, 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 (2 of 33) 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 new safety concerns for **JDQ443** 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 5 participants	Healthy participants 12 participants
Had at least 1 **serious adverse event**	0 of 8 0%	0 of 8 0%	0 of 5 0%	0 of 12 0%
Had at least 1 **other adverse event**	0 of 8 0%	2 of 8 25%	0 of 5 0%	0 of 12 0%
Left the trial due to an adverse event	0 of 8 0%	0 of 8 0%	0 of 5 0%	0 of 12 0%
Died	0 of 8 0%	0 of 8 0%	0 of 5 0%	0 of 12 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?

2 participants with moderate liver disease had other adverse events, which was headache. There were no additional adverse events during the trial.

What was learned from this trial?

Researchers learned about how the body processes **JDQ443** and its safety in people with and without liver disease.

The researchers concluded that:

- Mild and moderate liver disease slightly changed how the body processes **JDQ443**. However, the change was not meaningful.
- Because the trial ended early, there were too few participants with severe liver disease to conclude if it changed how the body processes **JDQ443**.
- There were no new safety concerns for **JDQ443** in this trial.

When this summary was written, the sponsor had no plans for future trials with **JDQ443**.

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:

Go to **www.novctrd.com** → Click **Clinical Trial Results** → Accept the terms **I accept** → Search by study number **CJDQ443B12103**

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

- **clinicaltrials.gov** – search using the number **NCT05329623**

Other trials of **JDQ443** may appear on the public website above. When there, search for **JDQ443** or opnurasib.

Full clinical trial title: A Phase 1, open-label, single-dose, multi-center, parallel group study to evaluate the pharmacokinetics of JDQ443 in participants with mild, moderate or severe hepatic impairment compared to matched healthy control participants

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