NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about the safety of TQJ230 and how the body processes it in people with and without mild 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 **TQJ230**, also called pelacarsen.

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: CTQJ230A12202
Drug studied: TQJ230
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 purpose of this trial was to help researchers learn if mild liver disease changes how the body processes the trial drug TQJ230. The researchers also wanted to learn about the safety of TQJ230 in people with and without mild liver disease.

Liver disease is a group of conditions that causes liver damage and scarring. Because the liver helps to process certain drugs, liver disease can change how the body processes drugs like TQJ230.

TQJ230 is a trial drug designed to treat cardiovascular disease. This trial did not look at the effects of TQJ230 on any health condition.

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.

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

- Did mild liver disease change how the body processed TQJ230?
- 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?

The trial ran for about 1 year. The trial began in November 2021 and ended in October 2022.

Who was in this trial?

17 participants received treatment in this trial. Participants' ages ranged from 43 to 74 years. Their average age was 60 years. The number of participants by sex and race is shown below.

Sex

9 Men	8 Women

Race

4 Black or African American	13 White

Out of the 17 participants:

- 9 participants were **healthy** and did not have liver disease
- 8 participants had **mild liver disease**

The trial took place in the United States.

What treatments did the participants receive?

The treatment in this trial was:

TQJ230. Participants received one 80 milligram (mg) dose as an injection under the skin.

The participants, researchers, and trial staff knew which treatment the participant received. Participants with mild liver disease could continue to take certain medicines for their condition.

What happened during this trial?

Before treatment — About 1 month

Trial doctors checked the participants' health to make sure they met the health requirements to join this trial.

Treatment — One time

Every participant received TQJ230 one time as an injection under the skin. After the injection, they stayed at the site for at least 4 days. Trial staff measured the amount of TQJ230 in the participants' blood and checked their general health.

The graphic below shows how many participants were assigned to each group.

After treatment — About 4 months

Participants returned to their trial site up to 3 times after receiving TQJ230 for follow-up visits. Trial staff measured the amount of TQJ230 in the participants' blood and checked their general health.

Trial staff also called them to check on their general health.

What were the main results of this trial?

Did mild liver disease change how the body processed TQJ230?

The researchers concluded that the body processed TQJ230 **about the same** in participants with mild liver disease compared to healthy participants.

While there were some slight changes, the researchers concluded the changes were **not meaningful.**

To find this out, the trial staff took many blood samples from each participant after they received TQJ230.

During the trial, the researchers measured:

- The total amount of TQJ230 in the blood
- The peak level of TQJ230 in the blood

Then, researchers compared these measures in participants with mild liver disease to healthy participants.

The total amount of TQJ230 was:

Slightly higher in some participants with mild liver disease compared to healthy participants.

The peak level of TQJ230 was:

Slightly higher in participants with mild liver disease compared to healthy participants.

Based on all the results, the researchers concluded that, overall, mild liver disease **did not have a meaningful change** on how the body processed TQJ230.

What adverse events did the participants have?

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.

This section is a summary of the adverse events that happened from the day participants received trial treatment until about 2 months 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 17 participants) had adverse events. None of the participants had adverse events that were considered serious. None of the participants left the trial due to an adverse event. The researchers concluded there were no new safety concerns for TQJ230 in this trial.

How many participants had adverse events?

Participants who:	Healthy participants 9 participants	Participants with mild liver disease 8 participants
Had at least 1 **serious adverse event**	0 of 9 0%	0 of 8 0%
Had at least 1 **other adverse event**	1 of 9 11%	1 of 8 13%
Left the trial due to an adverse event	0 of 9 0%	0 of 8 0%
Died during the trial	0 of 9 0%	0 of 8 0%

What serious adverse events did the participants have?

No participants had serious adverse events, and none died.

What other adverse events did the participants have?

2 participants had other adverse events.

The table below shows the other adverse events that happened.

	Healthy participants 9 participants	Participants with mild liver disease 8 participants
Headache	0 of 9 0%	1 of 8 13%
UTI Urinary tract infection	1 of 9 11%	0 of 8 0%

What was learned from this trial?

Researchers learned about how the body processed TQJ230 and its safety in participants with and without mild liver disease.

The researchers concluded that the body processed TQJ230 about the same in participants with mild liver disease compared to healthy participants. While there were some slight changes, the researchers concluded the changes were not meaningful.

The researchers concluded there were no new safety concerns for TQJ230 in this trial.

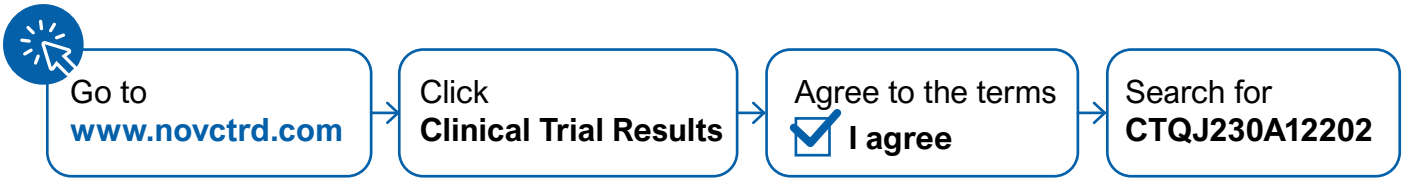
Researchers look at the results of many trials to learn about the safety and effect of new treatments.

There are other trials planned for TQJ230.

Where can I learn more about this and future trials?

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 **NCT05026996**

If more trials are planned, they will appear on the public websites below. When there, search for TQJ230, pelacarsen, or cardiovascular disease.

- **clinicaltrials.gov**
- **clinicaltrialsregister.eu/ctr-search**

Full clinical trial title: A single-dose, open-label, parallel-group study to assess the pharmacokinetics of pelacarsen (TQJ230) in participants with mild hepatic impairment compared to matched healthy participants

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

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