NOVARTIS

Clinical Trial Results Summary

Research Sponsor: Novartis

Drug Studied: Fevipiprant (QAW039)

Trial Number: CQAW039A2108

Plain Language Title: A trial to learn how much fevipiprant gets into the blood and about its safety in participants with liver disease and in healthy participants

Thank you!

Thank you to the participants who took part in the clinical trial for the trial drug fevipiprant. All of the participants helped the researchers learn more about how fevipiprant works and how safe it is to take.

Novartis sponsored this trial and reviewed the results of the trial when it ended. We at Novartis believe it is important to share what was learned from the results of this trial with the participants and the public. An independent organization prepared this summary of the trial results.

We hope this helps the participants understand their important role in medical research.

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

You can find more information about this trial on the website listed on the last page of this summary.

Overview of this trial

What was the purpose of this trial?

In this clinical trial, the researchers studied how much of a trial drug called fevipiprant got into the blood in participants with liver disease and in healthy participants without liver disease.

The researchers also studied the safety of fevipiprant in these participants.

The main questions the researchers wanted to answer in this trial were:

- Did the severity of liver disease affect how much fevipiprant got into the participants' blood?
- What medical problems did the participants have during the trial?

Keeping track of the participants' medical problems helped the researchers learn about the safety of fevipiprant.

Who was in this trial?

42 men and women participated in this clinical trial. Some of the participants had different severities of liver disease. Some were healthy participants with no liver disease.

What treatments did the participants take?

All of the participants in this trial took fevipiprant.

What were the main results of this trial?

Overall, the researchers learned that:

- The severity of liver disease affected how much fevipiprant got into the blood. The participants with more severe liver disease had higher levels of fevipiprant in the blood.
- 9.5% of the participants had medical problems during this trial. None of the medical problems were serious. None of the participants left the trial due to a medical problem.

More details about the results of this trial are included later in this summary.

What was the purpose of this trial?

Before a trial drug can be approved for patients to take, researchers do clinical trials to find out how safe it is and how it works. Fevipiprant was being developed as a possible treatment for asthma. Some people with asthma also have liver disease. So, it is important to know if fevipiprant is processed by the body differently in people with liver disease compared to people without liver disease.

One of the ways the body removes drugs from the blood is through the liver. The liver breaks down waste, nutrients, and some drugs from the blood. So, when the liver is not working normally, the amount of some drugs in the blood can increase. If this happens, a different dose of the drug could be needed.

In this trial, the researchers wanted to learn if participants with different severities of liver disease would need a different dose of fevipiprant compared to healthy participants without liver disease.

The main questions the researchers wanted to answer in this trial were:

- Did the severity of liver disease affect how much fevipiprant got into the blood?
- What medical problems did the participants have during the trial? Keeping track of the participants' medical problems helped the researchers learn about the safety of fevipiprant.

Who was in this trial?

To answer the questions in this trial, the researchers asked for the help of men and women with severe, moderate, or mild liver disease. They also asked for the help of healthy participants without liver disease.

To check the severity of the participants' liver disease, the researchers used a scoring system called the Child Pugh assessment. This system includes different measures of liver health. The trial doctors gave each participant a score depending on the results of their liver measurements. The higher the score, the more severe the participant's liver disease. Based on their score, each participant was assigned to 1 of 4 groups.

Everyone in the trial was 26 to 68 years old when they joined. The average age of the participants was 55 years.

The trial included 42 participants in the United States.

What treatments did the participants take?

All of the participants in this trial took fevipiprant as a pill by mouth.

The doses of fevipiprant were measured in milligrams, also known as mg.

During this trial, each participant knew what treatment they were taking. The trial staff and sponsor staff also knew what treatment each participant was taking.

The chart below shows the treatment that the participants took in the trial.

	Group 1	Group 2	Group 3	Group 4
	8 participants	8 participants	8 participants	18 participants
	Mild liver disease	Moderate liver disease	Severe liver disease	No liver disease
	450 mg fevipiprant			
	1 time			

What happened during this trial?

The trial started in May 2017 and ended in April 2019. Each participant was in the trial for up to about 8 weeks.

The chart below shows what happened during the trial.

Before the participants took treatment

Up to 2 weeks

The trial doctors checked the participants' health to make sure they could be in the trial.

While the participants took the treatment

Up to 6 days

The participants took fevipiprant 1 time.

The participants:

- Had their overall health checked and answered questions about any medical problems they were having
- Had blood and urine samples taken

After the participants took treatment

About 5 weeks

- The trial doctors and staff checked the participants' health and took blood and urine samples.
- The trial staff called the participants and asked them about any medical problems they were having within 30 days of their last visit.

What were the results of this trial?

This is a summary of the overall results from this trial. The individual results of each participant might be different and are not in this summary.

The results from several trials are needed to decide which treatments are safest and work best. Other trials may provide new information or different results. Always talk to a doctor before making any changes to your healthcare.

Did the severity of liver disease affect how much fevipiprant got into the blood?

Yes. Overall, the researchers found that the severity of liver disease affected how much fevipiprant got into the participants' blood. The participants with more severe liver disease had higher levels of fevipiprant in their blood.

The researchers wanted to know how much fevipiprant got into the participants' blood. To find out, the trial doctors took blood samples at different times before and after the participants took fevipiprant. The researchers studied:

- the average level of fevipiprant in the blood over 6 days, after the participants took it
- the highest level of fevipiprant in the blood after the participants took it

Knowing how much fevipiprant got into the blood helps researchers decide what dose to give participants in future trials.

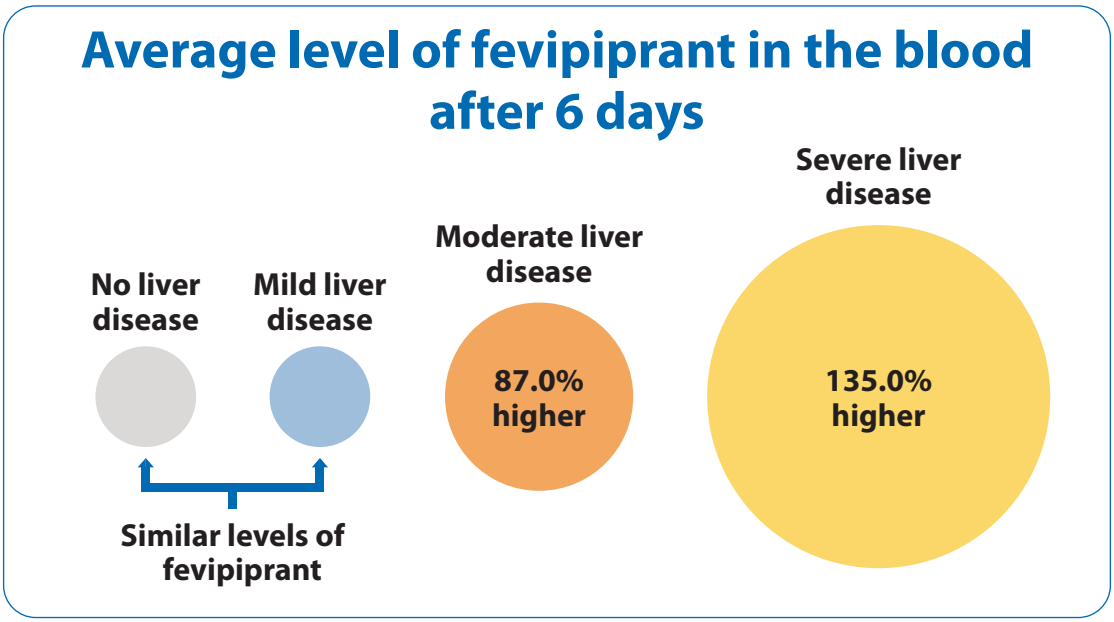
Overall, the researchers found that the average level and the highest level of fevipiprant in the blood were higher in participants who had more severe liver disease.

Average level of fevipiprant in the blood

The researchers measured the average level of fevipiprant in the blood in each participant. They combined the results of the participants in each group to find out the average level of fevipiprant in the blood over 6 days after the participants took it.

Over a period of 6 days, the researchers found that the average level of fevipiprant in the blood was:

- similar in the participants with mild liver disease and the participants without liver disease
- about 87.0% higher in the participants with moderate liver disease compared to the participants without liver disease
- about 135.0% higher in the participants with severe liver disease compared to the participants without liver disease

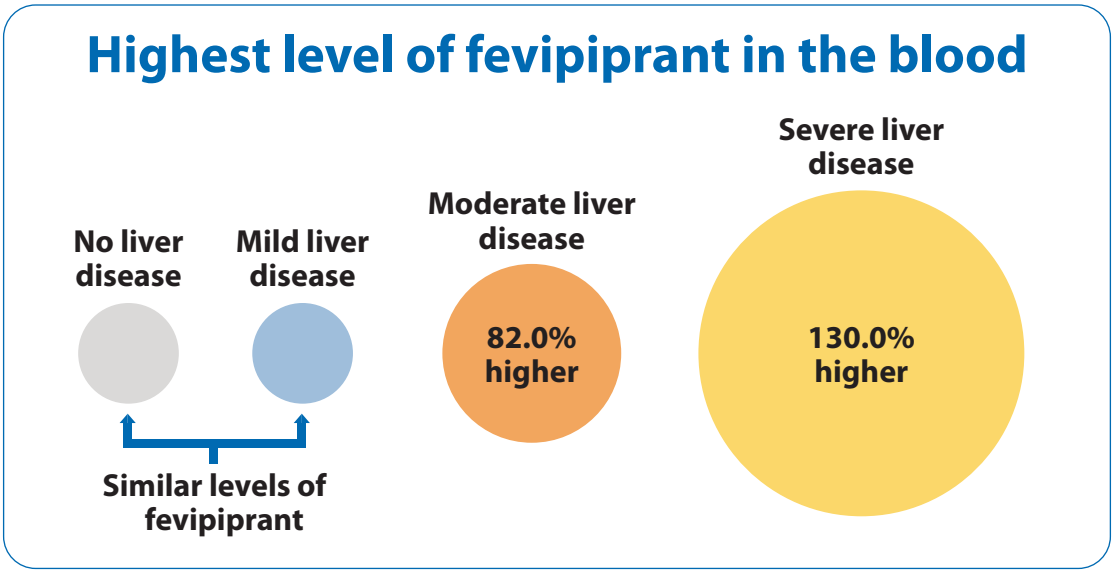


Highest level of fevipiprant in the blood

The researchers measured the highest level of fevipiprant in the blood in each participant. They combined the results of the participants in each group to find out the average highest level of fevipiprant in the blood after the participants took it.

The researchers found that the average highest level of fevipiprant in the blood was:

- similar in the participants with mild liver disease and the participants without liver disease
- about 82.0% higher in the participants with moderate liver disease compared to the participants without liver disease
- about 130.0% higher in the participants with severe liver disease compared to the participants without liver disease



The researchers also measured the levels of fevipiprant's metabolite. Metabolites are substances that form when fevipiprant is broken down by the body. The researchers did not find that the amount of the metabolite found in the blood changed depending on the severity of the participants' liver disease.

What medical problems happened during this trial?

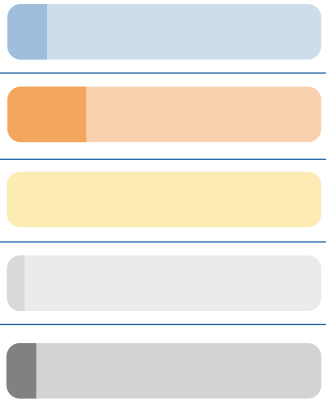
Medical problems that happen in clinical trials are called “adverse events”. An **adverse event** is any unwanted sign or symptom that participants have during a trial. An adverse event is considered “serious” when it is life-threatening, causes lasting problems, the participant needs hospital care, or results in death.

Adverse events may or may not be caused by the treatments in the trial. A lot of research is needed to know whether a treatment causes an adverse event. Doctors keep track of all the adverse events that happen in trials, even if they do not think the adverse events might be related to the treatments.

This section is a summary of the adverse events that happened during this trial.

Summary of adverse events

Treatment group	Participants who had adverse events	
Mild liver disease Out of 8 participants	12.5%	1 of 8
Moderate liver disease Out of 8 participants	25.0%	2 of 8
Severe liver disease Out of 8 participants	0.0%	0 of 8
No liver disease Out of 18 participants	5.6%	1 of 18
Total Out of 42 participants	9.5%	4 of 42



None of the participants had serious adverse events.
None of the participants left the trial due to adverse events.

What were the adverse events?

During this trial, no serious adverse events were reported, including deaths.

All of the adverse events in this trial happened in 1 participant each. The table below shows all of the adverse events that happened during this trial.

Adverse events in this trial

	Mild liver disease (Out of 8 participants)	Moderate liver disease (Out of 8 participants)	Severe liver disease (Out of 8 participants)	No liver disease (Out of 18 participants)	Total (Out of 42 participants)
Diarrhea	12.5% (1)	0.0% (0)	0.0% (0)	0.0% (0)	2.4% (1)
Headache	0.0% (0)	0.0% (0)	0.0% (0)	5.6% (1)	2.4% (1)
Decrease in brain function caused by liver disease (Hepatic encephalopathy)	0.0% (0)	12.5% (1)	0.0% (0)	0.0% (0)	2.4% (1)
Cold sores (Oral herpes)	0.0% (0)	12.5% (1)	0.0% (0)	0.0% (0)	2.4% (1)

For information about the adverse events in this trial, please see the scientific summary that can be found on the website noted at the end of the summary.

What was learned from this trial?

The information described above helped researchers learn more about how much fevipiprant gets into the blood in participants with liver disease and healthy participants with no liver disease. It also helped researchers learn how safe fevipiprant is in these participants.

The results presented here are for a single trial. This summary shows only the main results from this one trial in a small number of participants.

While this trial finished as planned, the results from other larger trials in patients with asthma did not support further development of fevipiprant as a treatment for asthma. So, fevipiprant is no longer being studied as a potential treatment for asthma.

Where can I learn more about this trial?

More information about the results of this trial can be found in the scientific results summary available on the Novartis Clinical Trial Results website.

- Go to www.novctrd.com.
- Once on the site, click **"Clinical trial results and trial summary for patients"** at the top right of the page.
- After accepting the terms, go to the bottom left of the page and click **"Search by study number"**.
- Type **"CQAW039A2108"** into the keyword search box and click **"Search"**.

If you would like to view the website in a language other than English, you can click the **"Google Translate"** button on the top right of the page.

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

You can find more information about this trial on the website listed below.

- www.clinicaltrials.gov Once you are on the website, type **"CQAW039A2108"** into the **"Other terms"** search box and click **"Search"**.

If more clinical trials are planned, they will be listed on the above public websites or www.novartisclinicaltrials.com. Search for **"QAW039" or "fevipiprant".**

Full trial title: An open-label, single-dose, parallel-group study to assess the pharmacokinetics of fevipiprant (QAW039) in patients with hepatic impairment compared to matched healthy subjects

Protocol number: CQAW039A2108

Thank you!

Clinical trial participants belong to a large community of participants around the world. They help researchers answer important health questions and test new medical treatments.

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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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