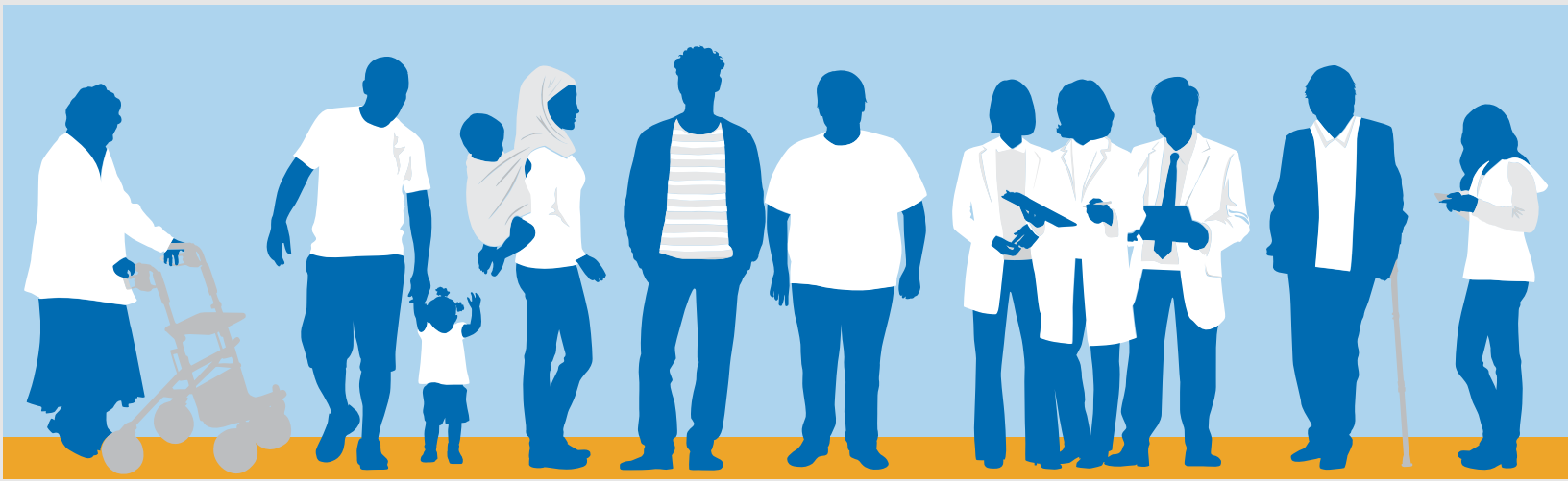
NOVARTIS

The safety of FIA586 and how the body processes it 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 **FIA586**.

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: CFIA586A02101
Drug studied: FIA586
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 liver disease changes how the body processes the trial drug FIA586. The researchers also wanted to learn about the safety of FIA586 in people with and without liver disease.

Many health authorities require a trial like this for certain types of drugs before they can approve them. Results from these trials can also change how doctors prescribe the drug for people with liver disease.

FIA586 is a trial drug designed to treat a type of liver disease called non-alcoholic steatohepatitis (NASH) with liver scarring. This trial did not look at the impact of FIA586 on NASH.

Liver disease is a group of conditions that cause liver damage and scarring. Over time, this damage and scarring can stop the liver from working well.

Because the liver helps to process certain drugs, liver disease can change how the body processes these drugs.

The main questions this trial was designed to answer:

- Did liver disease change how the body processed FIA586?
- 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 began in December 2021 and ended in June 2022. It was planned for the participants to be in the trial for about 6 days after taking the trial treatment. The trial staff followed up with participants after 1 month to check for any safety concerns.

Who was in this trial?

29 participants were in this trial – 14 men and 15 women. The participants were 52 to 70 years old. Their average age was 62.

Participants reported their race as:

- Asian – 1 participant
- Black or African American – 2 participants
- White – 26 participants

Out of the 29 participants:

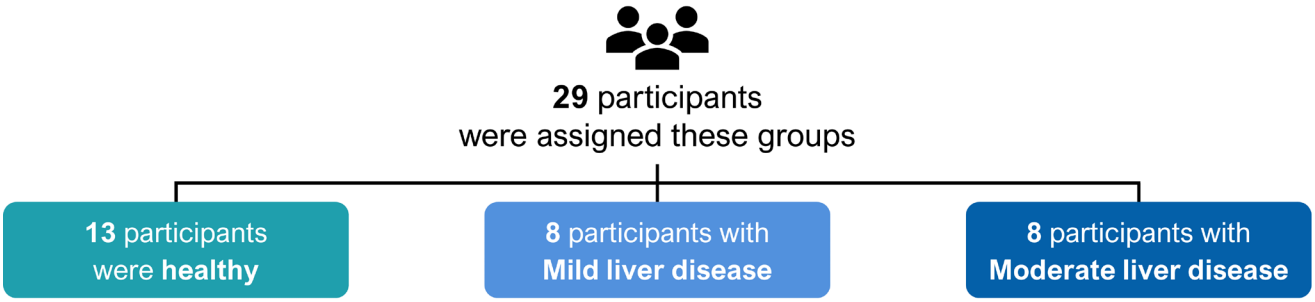
- 13 participants were considered **healthy** and did not have liver disease
- 16 participants had liver disease and were assigned to 1 of 2 groups based on the severity of their liver disease:
  - **Mild liver disease**
  - **Moderate liver disease**

This trial took place in the United States.

What trial treatments did the participants take?

Every participant took 350 milligrams (mg) of **FIA586** one time as pills.

The participant, trial staff, and researchers knew which treatment the participant took. Participants with liver disease continued to take certain medicines for their condition. The graphic below shows how many participants were assigned to each group.



What were the main results of this trial?

Did liver disease change how the body processed FIA586?

The researchers concluded that the body processed FIA586 **about the same** in participants with 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 took FIA586. The researchers measured:

- The **total amount** of FIA586 in the blood
- The **peak level** of FIA586 and time it took to **reach the peak level** in the blood
- How long FIA586 **stayed** in the blood

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

The **total amount** of FIA586 in the blood was:

About the same in participants with **mild liver disease**

Slightly higher in participants with **moderate liver disease**

The **peak level** of FIA586 was:

Slightly lower in participants with **mild liver disease**

About the same in participants with **moderate liver disease**

The time it took FIA586 to **reach the peak level** in the blood was:

Slightly longer for participants with **mild liver disease**

Slightly shorter for participants with **moderate liver disease**

The length of time FIA586 **stayed** in the blood was:

Slightly shorter for participants with **mild liver disease**

About the same for participants with **moderate liver disease**

Based on these results, the researchers concluded that the overall changes were not meaningful.

What adverse events did the participants have during this trial?

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.

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.

In this trial, researchers checked for any adverse events that happened during treatment and up to 30 days after taking the trial treatment.

None of the participants (0 of 29 participants) had adverse events or serious adverse events. No participants left the trial due to adverse events or died during this trial.

The researchers concluded there were no new safety concerns for FIA586 in this trial.

What was learned from this trial?

This trial helped researchers learn about the safety of FIA586 and how the body processed it in healthy people and people with liver disease.

The researchers concluded that the body processed FIA586 about the same in participants with mild or moderate liver disease compared to healthy participants. The researchers found no new safety concerns for FIA586 in this trial.

These are the results of a single trial. Other trials may have different results. This was one of many trials a drug goes through. This type of trial helped researchers learn about the safety of a trial drug in a small number of participants.

Where can I learn more about this and future trials?

For more information about this trial go to any of the following websites:

- **novctrd.com** – search using the study number **CFIA586A02101**
- **clinicaltrials.gov** – search using the number **NCT04993157**

If more trials are planned, they will appear on the public websites above. When there, search for **FIA586**, **liver disease**, or **hepatic impairment**.

Full trial title:

A Phase I, single-dose, open-label, parallel-group study to assess the pharmacokinetics, safety, and tolerability of FIA586 in participants with mild and moderate hepatic impairment compared to matched healthy participants

? 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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