NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about the effects of triclabendazole in children and adults with liver fluke infection caused by fasciola worms

Thank you!

Thank you to the participants who took part in the clinical trial for the treatment of **liver fluke infection**. Every participant helped to learn more about the trial drug **triclabendazole**, also called **EGA230**.

Novartis sponsored this trial. We believe 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: CEGA230B2404

Novartis drug studied: **triclabendazole**, also called **EGA230**

Sponsor: Novartis

If you were a participant and have any questions about the results, please talk to your 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 learn more about the effects of **triclabendazole** for children and adults with **liver fluke infection caused by fasciola worms**.

Liver fluke infection, also called fascioliasis, is caused by a worm called fasciola. People get infected with liver flukes when they eat contaminated food such as raw plants, or drink contaminated water.

After the worm enters the body, it infects and damages the liver and other organs.

Liver fluke infection can cause fever and stomach problems, such as feeling sick to the stomach, throwing up, pain, and diarrhea.

Triclabendazole, also called **EGA230**, is a trial drug that kills fasciola worms.

Triclabendazole has been approved for adults and children with liver fluke infection in France and the United States. It is also recommended by the World Health Organization for the treatment of liver fluke infection.

Trial drug
triclabendazole also called **EGA230**

Pronounced as
try-kluh-bend-uh-zole

The trial's purpose was to answer this main question:

- What medical problems, also called adverse events, happened during this trial?
  - **Adverse events** reported are any sign or symptom that participants had during this trial. Adverse events **may** or **may not** be caused by treatments in this trial.

How long was this trial?

The trial began in February 2022 and ended in March 2026. Each participant was in the trial for up to 3 months. The participants started the trial on different dates.

At the end of this trial, Novartis created a report of the trial results. This summary is based on that report.

Who was in this trial?

301 participants with **liver fluke infection** received treatment in this trial – 116 males and 185 females. Participants' ages ranged from 6 to 80 years. Their average age was 37 years.

Of the 301 participants:

- 246 participants had **acute liver fluke infection**, which meant the participant got the infection recently
- 39 participants had **chronic liver fluke infection**, which meant the participant had the infection for at least a few months
- 16 participants had an **unknown type of liver fluke infection** because doctors did not know when the infection started

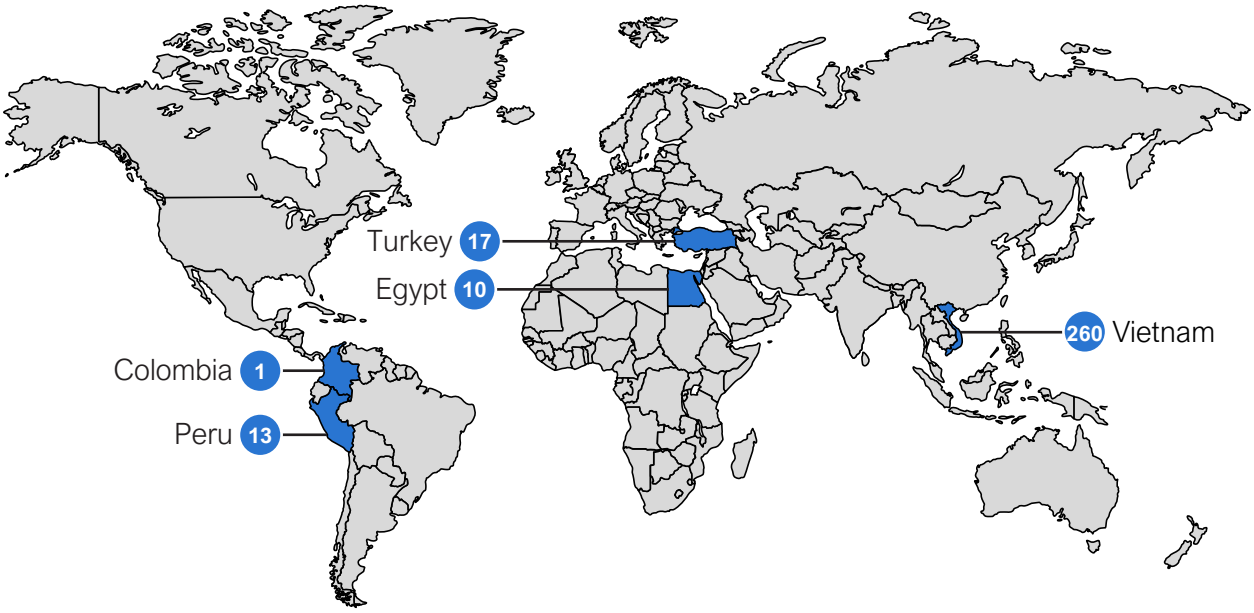
The table below shows the number of participants by race.

Race					
14	American Indian or Alaska Native	260	Asian	27	White

The participants could take part in this trial if they had **liver fluke infection** and:

- The liver flukes had not spread to certain organs, such as the lungs
- They had not taken medicine for **liver fluke infection** for at least the last 2 weeks

301 participants from 5 countries received treatment. The map below shows the number of participants who took part in each country.



What treatment did the participants receive?

The treatment in this trial was:

Triclabendazole – 2 doses of 10 milligrams per kilogram (mg/kg) of body weight, which were taken 12 hours apart.

Triclabendazole was taken by mouth as tablets.

The participants, researchers, and trial staff knew that all participants took **triclabendazole**.

What happened during this trial?

Before treatment — **Up to 2 weeks**

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

During treatment — **1 day**

301 participants took **triclabendazole** twice, 12 hours apart.

Trial staff asked participants who had certain **liver fluke infection** symptoms to stay at the hospital during treatment, so they could closely watch them.

After treatment — **Up to 3 months**

Trial staff checked participants for any medical problems and signs and symptoms of their **liver fluke infection** for up to 3 months 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?

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 do this even if they think the adverse events are not related to the trial treatments.

Researchers need results from many trials to decide if a drug or treatment causes an adverse event.

This section is a summary of the adverse events that happened from the day participants started the trial treatment until 3 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, requires hospital care, or results in death

Treatments in the trial **may** or **may not** cause adverse events.

139 out of 301 participants (46%) had adverse events, including serious and other adverse events.

- 7 out of the 301 participants (2%) had serious adverse events.
- No participants died.

The researchers concluded there were no new or unexpected safety concerns for **triclabendazole** in this trial.

What serious adverse events did the participants have?

7 participants had serious adverse events.

The table below shows the most common serious adverse event.

	Triclabendazole 301 participants
A buildup of pus in the liver Liver abscess	**2 of 301** 1%

What other (not including serious) adverse events did the participants have?

The table below shows the most common other adverse events.

	Triclabendazole 301 participants
Upper belly pain Abdominal pain upper	**34 of 301** 11%
Hives Urticaria	**34 of 301** 11%
Possible sign of liver damage Alanine aminotransferase increased	**28 of 301** 9%
Possible sign of liver damage Aspartate aminotransferase increased	**21 of 301** 7%
Possible sign of liver damage Gamma-glutamyltransferase increased	**16 of 301** 5%

What were the other results of this trial?

How many participants were cured of liver fluke infection 3 months after treatment?

3 months after treatment with **triclabendazole**, the number of participants who were cured of liver fluke infection was:

- 94% of participants with **acute liver fluke infection**
- 18% of participants with **chronic liver fluke infection**

To learn this, the researchers checked each participant for:

- **Signs and symptoms of liver fluke infection**, such as fever and stomach problems
- **Signs of liver fluke infection** in their blood tests and ultrasound images of their belly

What was learned from this trial?

Researchers learned more about the effects of **triclabendazole** in people with **liver fluke infection caused by fasciola worms**.

The researchers concluded that:

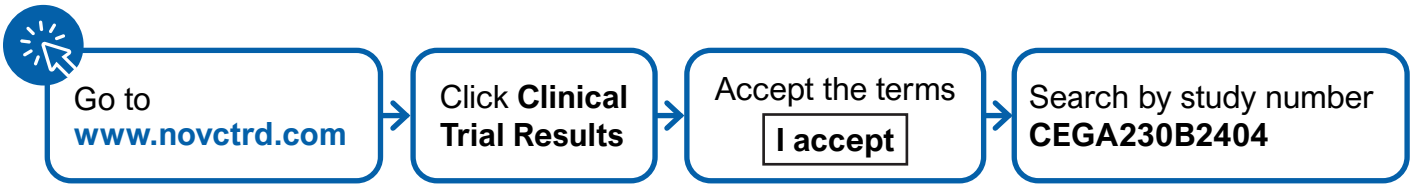
- There were no new or unexpected safety concerns for **triclabendazole** in this trial
- 94% of participants with **acute liver fluke infection** were cured 3 months after treatment
- 18% of participants with **chronic liver fluke infection** were cured 3 months after treatment

When this summary was written, Novartis had no plans for future trials of **triclabendazole** in people with **liver fluke infection**.

Where can I learn more about this trial?

To learn more about the results and adverse events in this trial, read the scientific summary of the results. It is 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 **NCT04230148**

Other trials of **triclabendazole** may appear on the public websites above. When there, search for **triclabendazole** or **EGA230**.

Full clinical trial title: A Phase IV, multi-center, open-label study to determine the safety, tolerability and clinical outcomes following oral administration of EGATEN™ (Triclabendazole) in patients (6 years of age or older) with fascioliasis



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

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