NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about the effects and safety of DFV890 in people with coronary heart disease

Thank you!

Thank you to the participants who took part in the clinical trial for **coronary heart disease** and **inflammation**. Every participant helped to learn more about the trial drug **DFV890**.

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: CDFV890F12201

Novartis drug studied: DFV890

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 and safety of **DFV890** for people with coronary heart disease. Participants in this trial also had signs of **inflammation**.



Coronary heart disease is a condition where the blood vessels to the heart become narrow or blocked. In coronary heart disease, fatty substances called **plaques** build up inside the blood vessels, which narrow them and block blood flow. This means less blood and oxygen gets to the heart, which can prevent it from pumping as much blood as it should.

Symptoms of coronary heart disease may include:

- Chest pain
- Trouble breathing
- Feeling weak or tired

The body often responds to plaques with inflammation. People with coronary heart disease and inflammation may have a higher chance of having a heart attack or stroke.

What is inflammation?

Inflammation is part of the body's response to damage or infection. However, too much inflammation can be harmful.



DFV890 is a trial drug created to lower inflammation by lowering the levels of certain proteins that cause inflammation. Researchers think lowering inflammation may lower the chance of a heart attack or stroke in people with coronary heart disease.



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

- Did DFV890 change signs of inflammation in the blood?
- 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 October 2023 and ended in December 2024. 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?

24 participants with coronary heart disease and inflammation received treatment in this trial – 22 men and 2 women. Participants' ages ranged from 48 to 79 years. Their average age was 64 years.

The table below shows the number of participants by race.

Race	
1	Black or African American
23	White

The participants could take part in this trial if they had:

- A heart attack at least a month before joining the trial
- A certain sign of inflammation in the blood

24 participants from 2 countries received treatment.

The participants took part in:

- Canada | 9 participants
- United States | 15 participants

What treatments did the participants receive?

The treatments in this trial were:

DFV890 – taken by mouth as tablets once a day. This trial looked at 4 doses of **DFV890**:

- 10 milligrams (mg)
- 25 mg
- 50 mg
- 100 mg

Placebo – taken by mouth as tablets once a day. It looks like the trial drug but does not have any drug in it. Researchers use a placebo to better understand the effect of a trial drug.

Researchers used a computer to randomly assign participants to their treatments.

The participants, researchers, and trial staff did not know what treatment the participants were receiving. Some trials are done this way because knowing what treatment the participants receive can affect the results of the trial. Doing a trial this way helps to make sure that the results are looked at with fairness across all treatments.

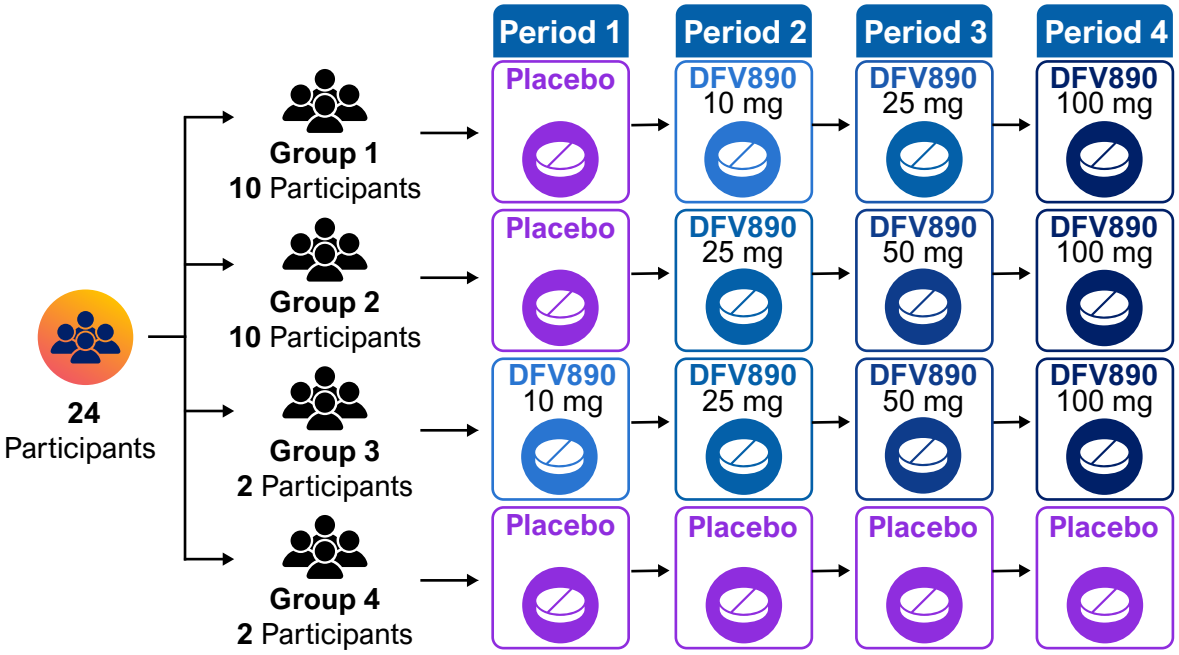
What happened during this trial?

Before treatment — Up to 2 months

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

During treatment — About 3 months

24 participants took treatment during 4 treatment periods that each lasted about 3 weeks. They were assigned to 1 of 4 groups.
The graphic below shows which treatment the groups received during each period.



After treatment — About 1 month

Trial staff checked participants' general health and for any medical problems for up to about 1 month after participants' last dose of treatment.

Trial staff checked the participants' general health throughout the trial.

What were the main results of this trial?

Did DFV890 change signs of inflammation in the blood?

Signs of inflammation went down 3 weeks after participants started taking **DFV890** compared to **placebo**. Overall, signs of inflammation went down more when participants took higher doses of **DFV890**.

To learn this, researchers measured 2 signs of inflammation in the blood:

- **Interleukin-6, or IL-6**
- **Interleukin-18, or IL-18**

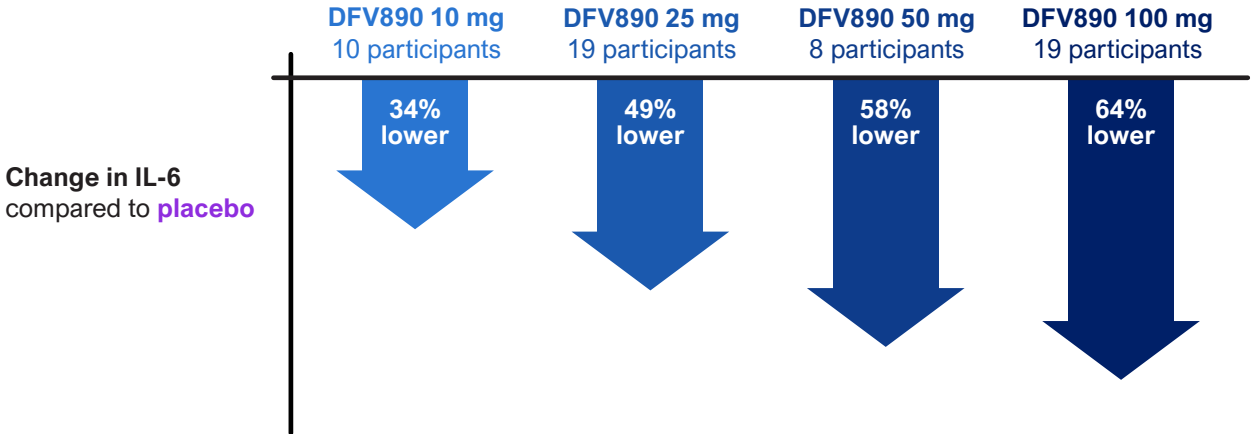
Researchers measured the levels of IL-6 and IL-18 in each participant's blood before treatment and after each 3-week treatment period. Then, researchers measured the average change in IL-6 and IL-18 compared to **placebo**.

What are IL-6 and IL-18?

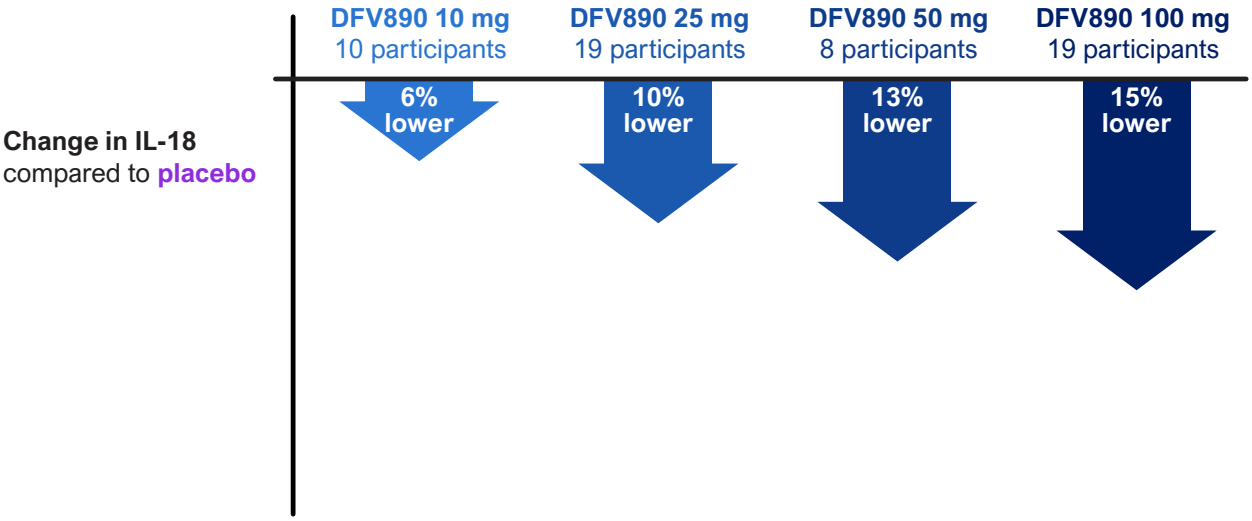
IL-6 and IL-18 are proteins in the blood. The amount of each protein goes up where there is inflammation in the body. High levels of these proteins may play a role in heart disease.

The graphs below show the change in the levels of IL-6 and IL-18 in participants' blood from before treatment to after each 3-week treatment period. These graphs only show results from participants who met all of the trial requirements.

Change in IL-6 after taking DFV890 compared to placebo



Change in IL-18 after taking DFV890 compared to placebo



What were the other results of this trial?

Did the level of DFV890 in the blood change at different dose levels?

As expected, the average level of **DFV890** in the blood at the end of each treatment period was higher when participants took higher doses of **DFV890**.

To learn this, the trial staff took blood samples from participants at the end of each treatment period. They measured the level of **DFV890** in the blood samples.

Researchers can use these results to decide how often and how much **DFV890** should be given in future trials.

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 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, requires hospital care, or results in death

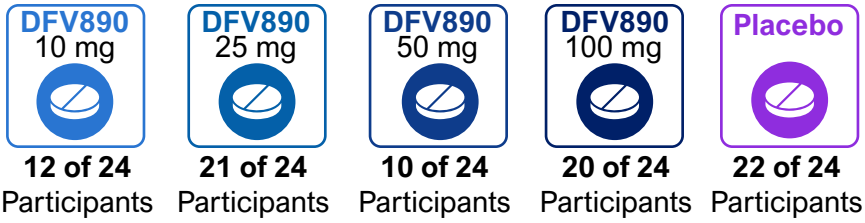
Treatments in the trial **may** or **may not** cause adverse events.

More than half of participants (13 of 24) had adverse events.

- 2 participants had serious adverse events
- No participants died

The researchers concluded there were no new safety concerns for **DFV890** in this trial.

The graphic below summarizes how many participants received each treatment by the end of all treatment periods.



What serious adverse events did the participants have?

2 participants had serious adverse events.

The following serious adverse events happened in 1 participant each during the treatment period that they took **50 mg DFV890**:

- **Block in blood flow to the brain for a short time (mini-stroke)** | Transient ischemic attack
- **Kidney stones** | Nephrolithiasis

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

13 participants had other adverse events.

The table below shows the other adverse events that happened in **2 or more** participants. Additional adverse events happened in fewer participants.

	10 mg DFV890 12 participants	25 mg DFV890 21 participants	50 mg DFV890 10 participants	100 mg DFV890 20 participants	Placebo 22 participants
Frequent, loose, or watery stool Diarrhea	0 of 12 0%	0 of 21 0%	0 of 10 0%	0 of 20 0%	2 of 22 9%
Muscle spasms	0 of 12 0%	0 of 21 0%	0 of 10 0%	0 of 20 0%	2 of 22 9%
Rash	1 of 12 8%	1 of 21 5%	0 of 10 0%	0 of 20 0%	0 of 22 0%
Rash with flat and bumpy spots Rash maculo-papular	1 of 12 8%	1 of 21 5%	0 of 10 0%	0 of 20 0%	0 of 22 0%

What was learned from this trial?

Researchers learned more about the effects and safety of **DFV890** in people with coronary heart disease and inflammation.

The researchers concluded that participants had:

- Lower levels of the signs of inflammation called IL-6 and IL-18 after taking **DFV890** compared to **placebo**. Overall, signs of inflammation went down more after taking higher doses of **DFV890**.
- More **DFV890** in their blood after taking higher doses compared to lower doses

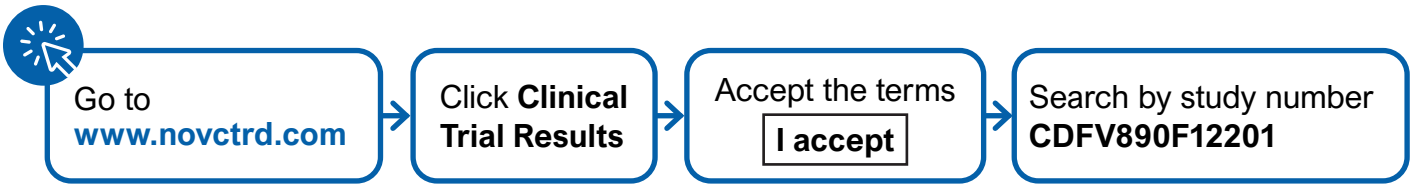
The researchers concluded there were no new safety concerns for **DFV890** in this trial.

When this summary was written, the sponsor had no plans for future trials of **DFV890** in people with coronary heart disease and inflammation.

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 **NCT06031844**

Other trials of **DFV890** may appear on the public websites above. When there, search for **DFV890**.

Full clinical trial title: A randomized, placebo-controlled, parallel-group, investigator- and participant-blinded Phase 2a study to investigate the efficacy, safety, and tolerability of DFV890 for inflammatory marker reduction in adult participants with coronary heart disease and elevated hsCRP



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