

Clinical Trial Results Summary

A clinical trial to learn more about the effects and safety of DFV890 in people with knee osteoarthritis

Thank you!

Thank you to the participants who took part in the clinical trial for **knee osteoarthritis**. Every participant helped to learn more about the trial drug **DFV890** and knee osteoarthritis.

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: CDFV890B12201

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 about the effects and safety of **DFV890** in people with knee osteoarthritis.



Knee osteoarthritis is a long-term condition in which the cartilage in the knee joint is damaged and wears away over time. When this happens, the bones in the knee joint rub together. This can cause symptoms of knee pain and stiffness especially when moving the knee.

Cartilage is the bendable tissue that covers the ends of bones, so they don't rub together. It cushions the bones, like a shock absorber, and helps the knee move smoothly.

People with knee osteoarthritis may also have **inflammation** in the knee. This inflammation can be caused by knee osteoarthritis, or can lead to knee osteoarthritis.



DFV890 is a trial drug created to lower inflammation. Researchers think lowering inflammation may lessen the symptoms of knee osteoarthritis.

What is inflammation?

Inflammation is part of the body's response to damage or infection. However, too much or long-lasting inflammation can be harmful, such as causing damage to healthy tissue or making arthritis worse.



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

- Did DFV890 change participants' knee pain?
- 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 September 2021 and ended in December 2024. It was planned for the participants to be in the trial for about 5 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?



115 participants with knee osteoarthritis received treatment in this trial – 22 males and 93 females. The participants' average age was 64 years.

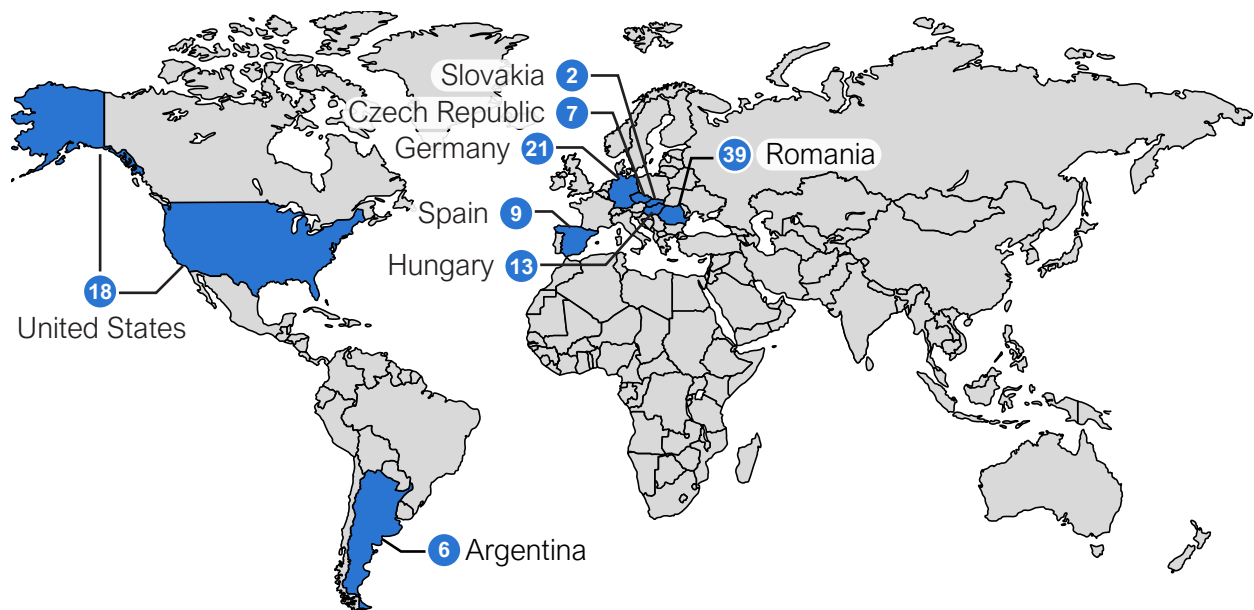
The table below shows the number of participants by race.



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

- Mild to moderate knee osteoarthritis
- Knee pain most days of the week
- Inflammation in the knee based on magnetic resonance imaging, also called MRI
- A sign of inflammation based on a blood test result for hsCRP (high-sensitivity C-reactive protein)

115 participants from 8 countries received treatment. The map below shows the number of participants who took part in each country.



What treatments did the participants receive?

The treatments in this trial were:



DFV890 – taken by mouth as tablets twice a day. For the first 2 weeks, the dose of **DFV890** was 10 milligrams (mg). Then, the dose was 25 mg for the next 10 weeks.



Placebo – taken by mouth as tablets twice 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.

Participants could take certain other medicines for knee osteoarthritis, such as paracetamol, also known as acetaminophen. These could be taken along with the above treatments during the trial.

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

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

About 6 weeks



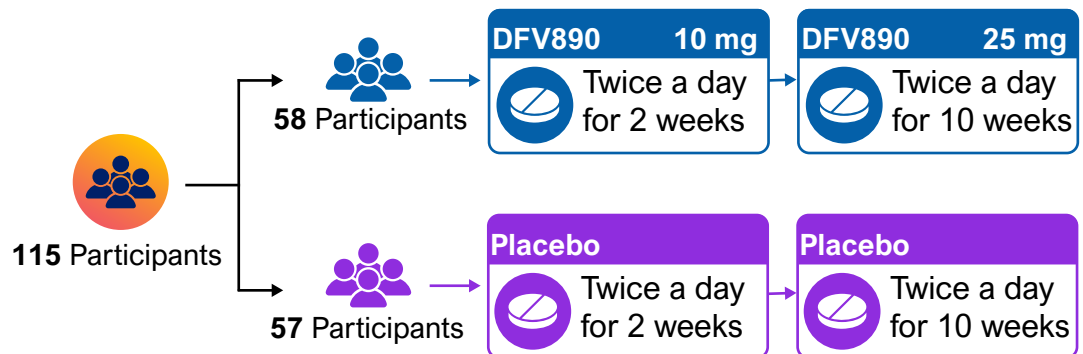
The trial staff checked to make sure the participants could be in this trial.

During treatment

3 months



The graphic below shows how many participants were assigned each treatment.



After treatment

1 month



Trial staff checked participants for any medical problems for up to 1 month 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?

Did DFV890 change participants' knee pain?



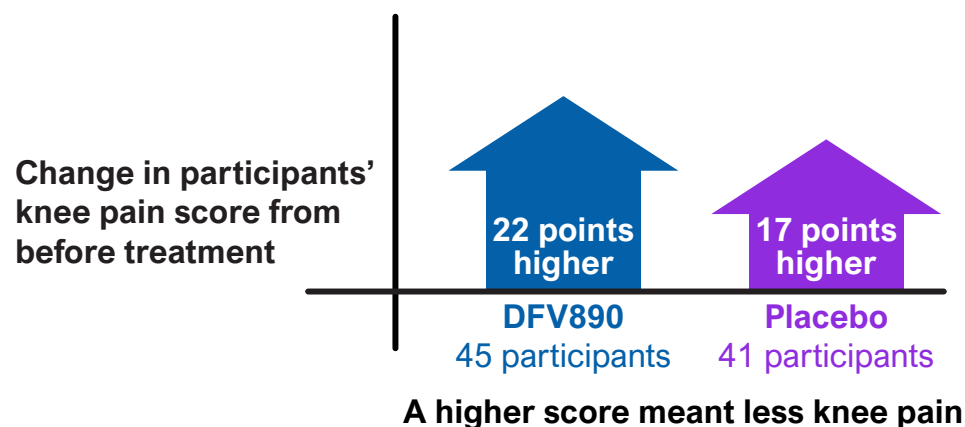
Participants who took **DFV890** had slightly less knee pain than those who took **placebo**.

To learn this, participants answered questions about their knee pain at many time points during the trial. Based on their answers, researchers scored their pain level. **A higher score meant less knee pain.**

Then, researchers compared the change in each participant's knee pain score from before treatment to about 3 months after starting treatment.

Change in participants' knee pain score from before treatment to 3 months after starting treatment

The graph below only shows results from participants who met all of the trial requirements.



What were the other results of this trial?

Did DFV890 lower inflammation in the knee and the whole body?



Participants who took **DFV890** had less knee inflammation than those who took **placebo**. They also had less inflammation in the whole body.

To learn about **knee inflammation**, researchers used magnetic resonance imaging, or MRI, to look at images of participants' knees.

Researchers compared changes in the images from before treatment to after treatment.

To learn about **inflammation in the whole body**, researchers looked at a blood test for a sign of inflammation in the participants' blood. This test measured hsCRP (high-sensitivity C-reactive protein). Higher levels of hsCRP are a sign of more inflammation.

Researchers compared changes in these measures from before treatment to during and after treatment.

Did DFV890 affect knee pain or other symptoms?



Participants who took **DFV890** had slightly less severe knee pain and certain other symptoms of knee osteoarthritis compared to those who took **placebo**. Both groups had about the same change in their ability to play sports or do other activities.

To learn this, researchers scored participants' answers to questions about:

- Their knee pain, stiffness, and how often they felt pain or stiffness
- Their ability to complete daily tasks, such as climbing stairs and sitting
- Their ability to play sports or do other activities
- How their knee pain affects their quality of life

Researchers compared changes in the scores from before treatment to during and after treatment.

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 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.



Over half the participants (64 of 115) had adverse events:

- 2 participants had serious adverse events
- No participants died
- More participants who took **DFV890** had adverse events compared to those who took **placebo**

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

What serious adverse events did the participants have?

2 participants had serious adverse events.

1 participant who took **DFV890** had these serious adverse events:

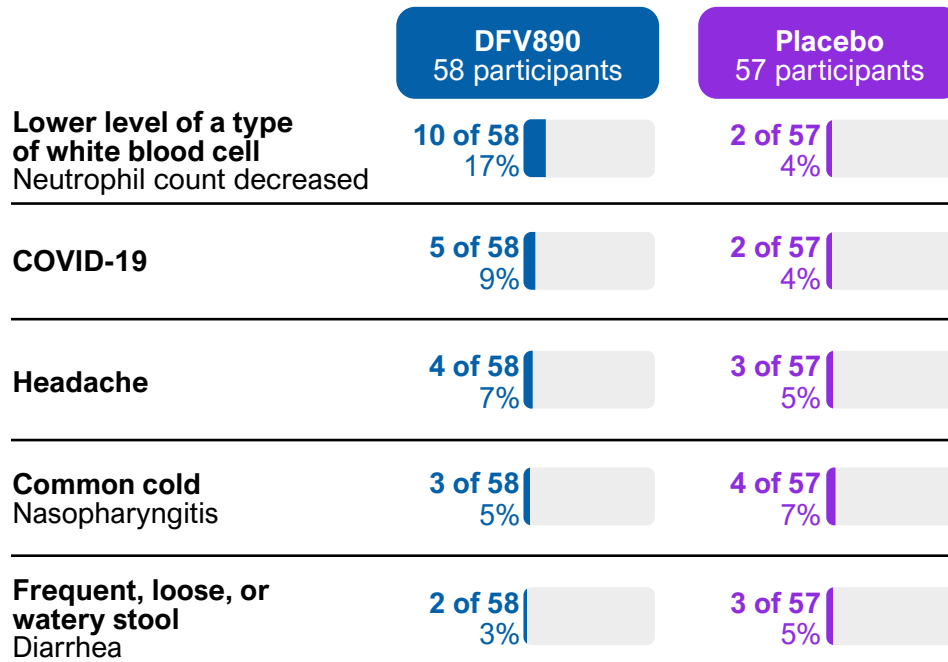
- **Bulge near the groin that needed surgery** | Inguinal hernia that was repaired surgically
- **Lung infection during the hospital stay after surgery** | Post-operative interstitial pneumonia

1 participant who took **placebo** had this serious adverse event:

- **Irregular heartbeat that needed a procedure to restore normal heart rhythm** | Atrial fibrillation with hospitalization for cardioversion

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

The table below shows the most common other adverse events that happened in **5 or more** participants. Additional other adverse events happened in fewer participants.



What was learned from this trial?

Researchers learned about the effects and safety of **DFV890** in people with knee osteoarthritis.



The researchers concluded that, compared to those who took the **placebo**, participants who took **DFV890** had:

- Slightly less knee pain on average
- Less knee inflammation and inflammation in the body
- Slightly less severe knee pain and certain other symptoms of knee osteoarthritis. About the same change in their ability to play sports or do other activities.

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

When this summary was written, Novartis had no plans for future trials of **DFV890** in people with knee osteoarthritis.

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:



Go to
www.novctrd.com

Click **Clinical
Trial Results**

Accept the terms
 I accept

Search by study number
CDFV890B12201

For more information about this trial, go to any of these websites:

- clinicaltrials.gov – search using the number **NCT04886258**
- euclinicaltrials.eu – search using the number **2023-507559-30**

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

Full clinical trial title: A randomized, two-arm, placebo-controlled, participant and investigator-blinded study investigating the efficacy, safety and tolerability of DFV890 in patients with symptomatic knee osteoarthritis



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

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