NOVARTIS

The effects and safety of DFV890 in people with COVID-19 pneumonia

Thank you!

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

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.

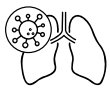
We hope this helps the participants understand their important role in medical research.

Trial information

Trial number: CDFV890D12201
Drug studied: DFV890
Sponsor: Novartis

What was the main purpose of this trial?

The main purpose of this trial was to learn if DFV890, combined with standard of care, could lower the participants' predicted chance of dying from COVID-19 pneumonia in the intensive care unit (ICU). To find this out, the clinical trial team compared health measures of participants who received DFV890 with standard of care to those who received only standard of care (typical treatments for COVID-19 pneumonia).



COVID-19 pneumonia, coronavirus disease 2019, is a type of lung infection caused by the SARS-CoV-2 virus. It causes lung inflammation that fills the lungs with fluid and leads to cough and trouble breathing. COVID-19 pneumonia can be life-threatening.

Inflammation is the immune system's response to infection that brings many cells and proteins to the infected area of the body. Sometimes, the immune system can overreact to an infection and cause inflammation that can damage the body.

DFV890 is a trial drug designed to block certain immune system proteins that cause inflammation. This may prevent the immune system from overreacting to an infection.

The main questions this trial was designed to answer:

- Did DFV890 reduce the predicted chance of dying in the ICU?
- What medical problems did the participants have during this trial?
  Keeping track of the medical problems helped to learn about the safety of DFV890.

Main results: After about 2 weeks, both groups had almost the same predicted chance of dying in the ICU. The predicted chance of dying in the ICU went down for both groups. The clinical trial team concluded there were no safety concerns for DFV890.

How long was this trial?

The trial began in May 2020 and ended in December 2020. It was planned for the participants to be in the trial for about 7 weeks.

Who was in this trial?

143 participants were in this trial – 97 men and 46 women. 142 participants received treatment. 22 participants did not complete this trial. Of the 22 participants, most died from problems related to COVID-19 pneumonia. The participants were 19 to 79 years old. Their average age was 61.

Every participant in this trial was hospitalized with COVID-19 pneumonia. A person couldn't be in this trial if they had other infections or if a doctor felt they wouldn't survive the next 24 hours, regardless of treatment.

This trial took place in Argentina, Brazil, Denmark, Germany, Hungary, India, Mexico, the Netherlands, Peru, the Russian Federation, South Africa, and Spain.

Visit novctrd.com for more information about:

- Who could and could not be in this trial
- The participants in this trial, such as their age, gender, and race
- Reasons why the participants did not complete the trial

Use trial number **CDFV890D12201** to find the scientific summary.

What trial treatments did the participants receive?

A computer program was used to randomly assign each participant to one of these treatment groups:

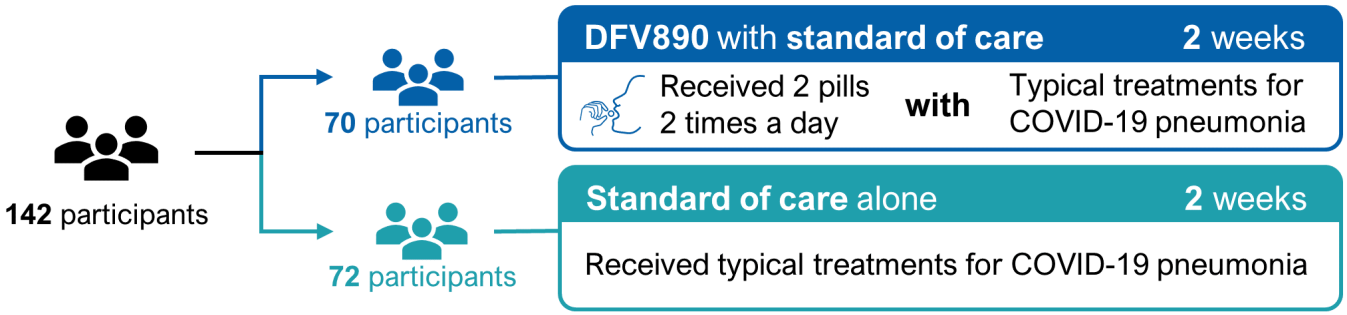
- DFV890 with standard of care
- Standard of care alone

Standard of care included the typical treatments doctors use to treat patients with severe COVID-19 pneumonia, such as:

- Oxygen through a mask
- A ventilator (a machine to help your lungs breathe)
- Medicines that lower inflammation and treat infection

Using a computer program to assign the treatments helped make sure the team compared the results as fairly as possible. Everyone knew which treatment the participants received.

The graphic below shows how many participants were in each treatment group.



What were the main results of this trial?

This is a summary of the overall results of this trial. Individual results from each participant may be different and are not included in this summary.

Researchers need many trials to learn if a drug or other treatment is safe and works well. Other trials may provide new information or different results.

Always talk to a doctor before making any changes to your health care.

The **clinical trial team** is a group of experts at Novartis who work together to analyze and determine the results from clinical trial findings.

Did DFV890 reduce the predicted chance of dying in the ICU?

No, overall there was no meaningful difference in the predicted chance of dying in the ICU between the 2 groups. After about 2 weeks, the predicted chance of dying went down almost the same amount in both groups.

To find this out, the clinical trial team compared the participants' APACHE II scores before treatment to their scores after 2 weeks of treatment or when they left the hospital, if sooner.

APACHE II (Acute Physiology and Chronic Health Evaluation) is a measure that doctors use to predict a person's chance of dying while in the ICU. APACHE II scores range from 0 to 71. As a participant's score goes **down**, their predicted chance of dying in the ICU goes **down**. The score is based on the participant's:

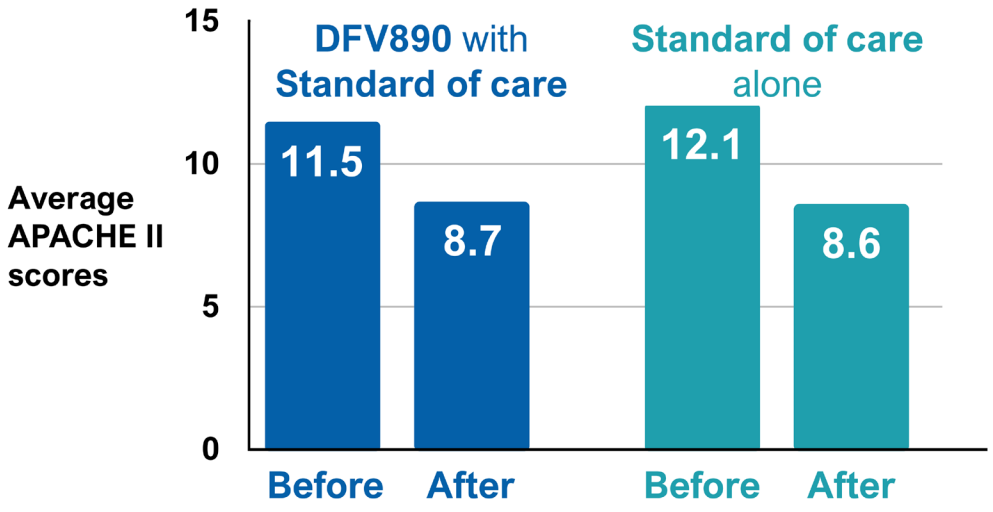
- Age
- Vital signs, like body temperature, blood pressure, heart rate, and breaths per minute
- Blood oxygen levels
- Blood tests that show signs of disease and organ damage
- Assessment of nervous system health and certain chronic health conditions

The clinical trial team found that the participants who received:

- **DFV890** with **standard of care** had their average score go **down** from 11.5 to 8.7
- **Standard of care** alone had their average score go **down** from 12.1 to 8.6

The participants' APACHE II scores

The participants' average scores before treatment compared to their scores after 2 weeks of treatment or when they left the hospital, if sooner.



What medical problems did the participants have during this trial?

Medical problems that happen during trials are called “adverse events”. Trial doctors looked for any adverse events during the trial. The participants also reported adverse events.

Many trials are needed to know if a drug or treatment causes an adverse event. 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.

An adverse event is:

- Any **unwanted sign or symptom** 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.

The adverse events in this section include those that happened during treatment and up to 1 month after completing treatment.

More than half of the participants (80 of 142 participants) reported adverse events. 27 participants reported adverse events that were considered serious. Of those participants, 16 died. Most of the deaths were from problems related to COVID-19 pneumonia. The clinical trial team concluded there were no safety concerns for DFV890.

What serious adverse events did the participants have?

27 of 142 participants reported a total of 40 serious adverse events. The table below shows the serious adverse events that happened to at least **3 or more participants.**
Other serious adverse events happened in fewer participants.

	DFV890 with **standard of care** **70** participants	**Standard of care** alone **72** participants
Lungs can’t get enough oxygen into the blood Respiratory failure	6% 4 of 70	6% 4 of 72
COVID-19 pneumonia that got worse	3% 2 of 70	3% 2 of 72
Life-threatening infection Sepsis	1% 1 of 70	3% 2 of 72
Death	11% 8 of 70	11% 8 of 72

Most of the deaths were from problems related to COVID-19 pneumonia.

What other adverse events did the participants have?

18 of 142 participants had adverse events that were not considered serious. The table below shows these adverse events that happened in at least **6 or more participants**. Other adverse events happened in fewer participants.

	DFV890 with **standard of care** **70** participants	**Standard of care** alone **72** participants
Low number of red blood cells Anemia	7% 5 of 70	7% 5 of 72
High blood sugar Hyperglycemia	6% 4 of 70	3% 2 of 72

Visit novctrd.com for more information about the adverse events that happened during this trial.

What other results were learned?

The clinical trial doctors looked at many measures of COVID-19 pneumonia symptoms. The clinical team found that all measures between the groups were about the same by the end of the trial.

However, there were some small differences after treatment ended. A slightly higher number of participants who received DFV890 with standard of care:

- Were able to survive without needing a ventilator
- Had slightly less severe COVID-19 pneumonia based on the trial doctor's assessment of their health status

During the first week of treatment, blood tests measuring a sign of inflammation showed that it went down faster in the DFV890 group. However, after 2 weeks of treatment, the sign of inflammation was about the same amount in the 2 groups.

What was learned from this trial?

This was the first trial to learn about DFV890 in participants with COVID-19 pneumonia who also received standard of care. The clinical trial team concluded that DFV890 with standard of care did not lower the participants' APACHE II scores more than standard of care of alone. That means the participants' predicted chance of dying in the ICU was about the same in both groups. The team found no safety concerns for DFV890.

The clinical trial team also found that DFV890 had an effect on a sign of inflammation. However, more trials are needed to study the effect of DFV890 with other conditions that involve inflammation.

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 learned 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 **CDFV890D12201**
- clinicaltrials.gov – search using the number **NCT04382053**
- clinicaltrialsregister.eu/ctr-search/search – search using the number **2020-001870-32**

If more trials are planned, they can be found on the public websites above. When there, search for **DFV890.**

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

Full trial title:
Phase 2, randomized, controlled, open label multi-center study to assess efficacy and safety of DFV890 for the treatment of SARS-CoV-2 infected patients with COVID-19 pneumonia and impaired respiratory function.

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