NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn about the effects and safety of MP0420 in people with mild to moderate COVID-19

Clinical trial protocol number: MP0420-CP302 or CSKO136A12201J

Thank you!

Thank you to the participants who took part in the clinical trial for the drug **MP0420**, also known as **ensovibep** or **SKO136.**

All of the participants helped the researchers learn about how MP0420 works in people with **mild to moderate COVID-19**. Molecular Partners and Novartis partnered to run this clinical trial and 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.

? **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.

Why was the research needed?

Researchers are looking for a better way to treat mild to moderate COVID-19. **COVID-19** is a disease caused by the virus SARS-CoV-2. Common symptoms include fever, cough, sore throat, muscle or body aches, tiredness, headache, and shortness of breath (trouble breathing). Most people with COVID-19 have mild or moderate symptoms, but some people have severe or life-threatening symptoms that require them to be hospitalized.

MP0420 is a trial drug designed to block the COVID-19 virus from infecting cells in the body. Researchers think that blocking the virus may lower the amount of virus in the body.

Trial purpose

The main purpose of this trial was to learn about the effects and safety of different doses of MP0420 for people with mild to moderate COVID-19 for up to 3 months after each participant received treatment one time.

The main questions the researchers wanted to answer in this trial were:

- Did MP0420 lower the amount of COVID-19 virus in participants over 8 days after treatment?
- What medical problems did the participants have during the trial?

How long was this trial?

This trial was designed to have 2 parts:

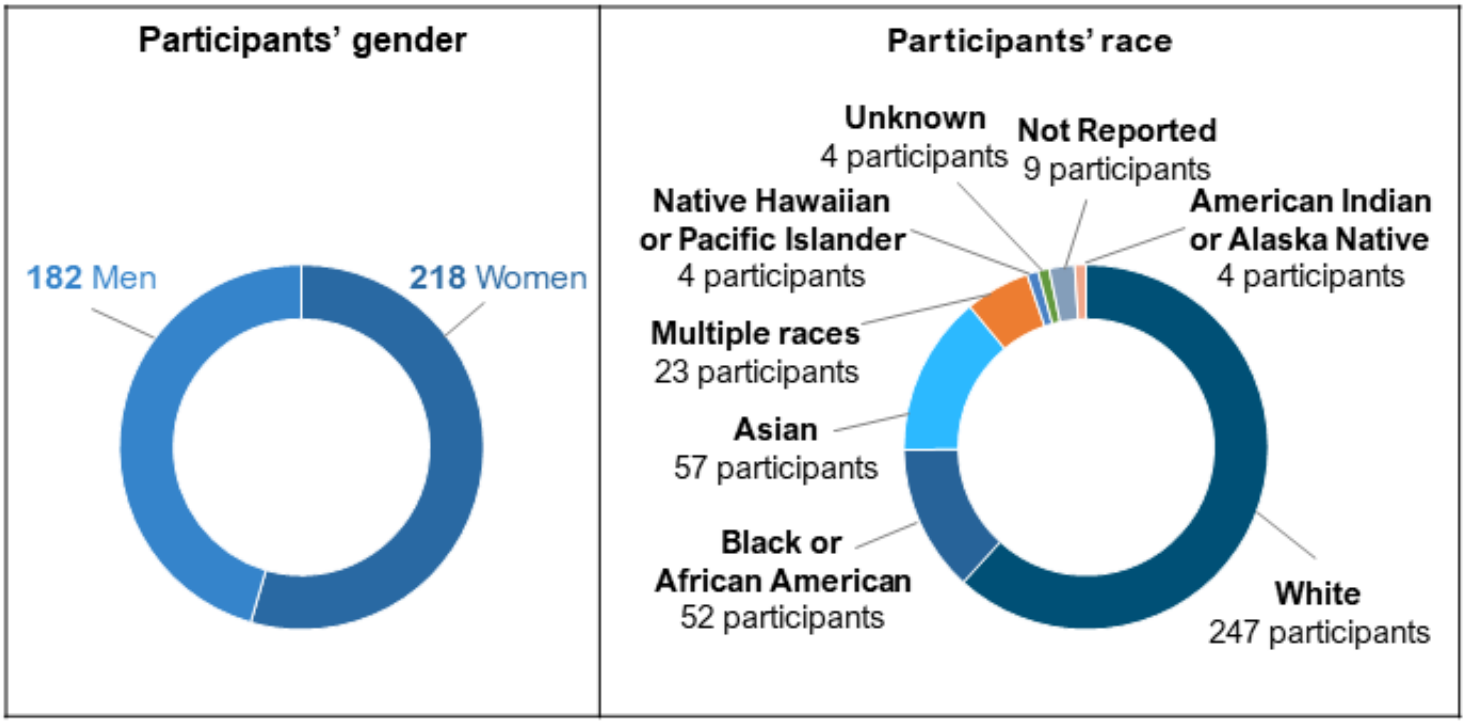
- **Part 1** started in May 2021 and ended January 2022. Part 1 compared the safety and effects of different doses of MP0420, so researchers could choose which dose to use in Part 2. The length of time each participant could be in the study was about 3 months.
- **Part 2** never started. Part 2 would have learned more about the safety and effects of the dose of MP0420 chosen in Part 1 compared to a placebo. A **placebo** looks like the trial drug but does not have any trial drug in it.

Why did Part 2 not start?

The reason was that other treatments for COVID-19 became available during the time it took to complete Part 1. Since other treatments were an option, it was no longer appropriate to give some participants a placebo in Part 2.

Who was in this trial?

400 participants with COVID-19 received treatment in this trial. Participants' ages ranged from 18 to 81 years. Their average age was 41 years.



The participants could take part in this trial if they:

- Had a positive COVID-19 test and 2 or more COVID-19 symptoms
- Had not used any prescription medicine to treat COVID-19 – participants who had gotten a COVID-19 vaccine before they got sick could take part
- Had no other serious infections or health conditions

400 participants from 5 countries received treatment. The map on the next page shows the number of participants who took part in each country.

What treatments did the participants receive?

The treatments in this trial were:

MP0420, also known as ensovibep or SKO136, which was received once through a needle in a vein as an infusion for 60 minutes. This trial looked at 3 doses of MP0420:

- **High dose**: 600 milligrams (mg)
- **Medium dose**: 225 mg
- **Low dose**: 75 mg

Placebo, which looks like the trial drug but does not have any trial drug in it. The placebo was received once through a needle in a vein as an infusion for 60 minutes. Using a placebo helps researchers better understand the effect of a trial drug.

Researchers randomly assigned participants to treatment groups using a computer system.

In this trial, none of the participants, trial doctors, or trial staff knew 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?

This shows what happened during Part 1 of this trial. Part 2 did not happen.

Up to 3 days before treatment

Before treatment

Trial doctors checked the participants' health, COVID-19 test results, and COVID-19 symptoms to make sure they could be in this clinical trial.

One 60-minute infusion

During treatment

400 participants received 1 of these treatments:

- **High dose of MP0420** (100 participants)
- **Medium dose of MP0420** (98 participants)
- **Low dose of MP0420** (102 participants)
- **Placebo** (100 participants)

Researchers checked the amount of COVID-19 virus in participants, COVID-19 symptoms, and general health throughout the trial.

Up to 3 months after treatment

After treatment

Participants returned to their trial site up to 8 times after receiving their dose of treatment for follow-up visits to check the amount of COVID-19 virus, COVID-19 symptoms, and general health.

What were the main results of this trial?

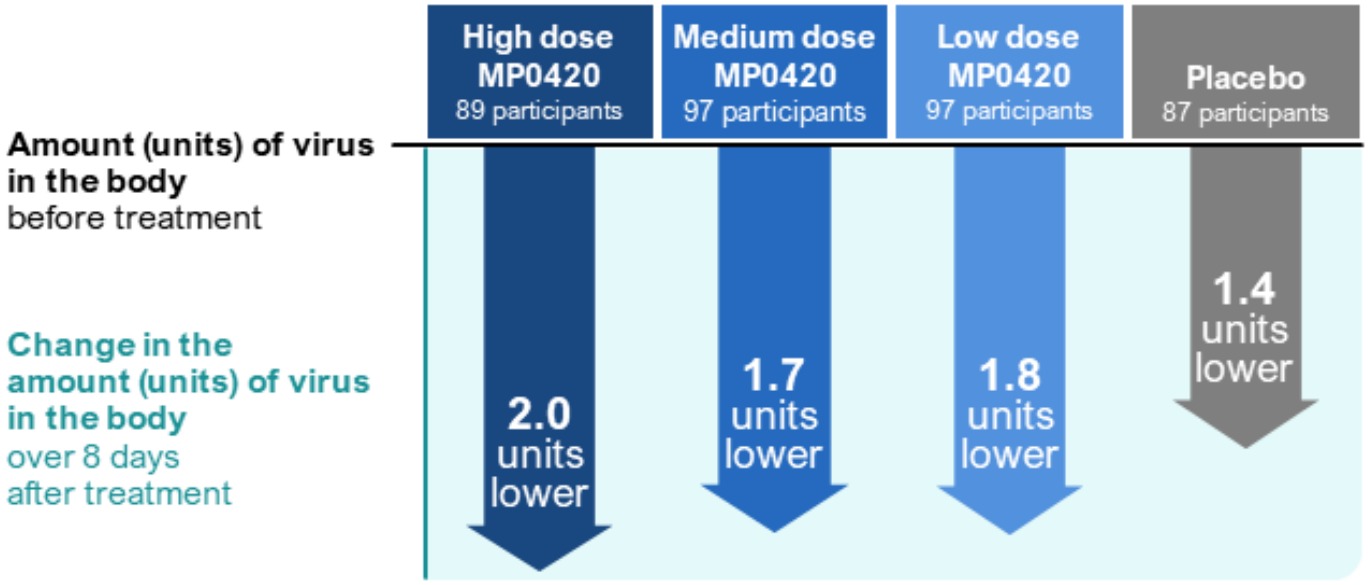
Did MP0420 lower the amount of COVID-19 virus in participants over 8 days after treatment compared to the placebo?

Yes, all the doses of MP0420 lowered the amount of virus in participants more than the placebo over 8 days after treatment.

The researchers took nasopharyngeal swabs from participants to measure the amount of COVID-19 virus in their bodies. A nasopharyngeal (NP) swab inserts a swab deep inside the nose where it meets the throat. The participants had NP swabs at 3, 5, and 8 days after receiving trial treatment. The researchers measured how much the amount of virus went down over time in the participants who received MP0420 compared to placebo. If the amount of virus in the body went down, it may mean the treatment has an effect.

How much the amount of virus in participants went down from before treatment to over 8 days after treatment

The graph below does not include participants who did not have the amount of virus measured at the start of the trial.



What were the other results of this trial?

Were the participants who received MP0420 less likely to need hospital care or die compared to those who received the placebo?

Yes, the participants who received any dose of MP0420 were 78% less likely to receive hospital or emergency room (ER) care for COVID-19 or die compared to those who received the placebo.

To learn this, the researchers kept track of how many participants in each treatment group:

- Received at least 24 hours of care at a hospital for COVID-19
- Received care at an emergency room (ER) for COVID-19
- Died from any cause

They compared the percent of all participants who received MP0420 to those who received the placebo 29 days after they received trial treatment.

Did participants who received MP0420 recover more quickly compared to those who received the placebo?

Yes, the researchers concluded that, on average, participants who received any dose of MP0420 had their COVID-19 symptoms become mild or go away sooner than those who received the placebo.

Participants who received any dose of MP0420 had their symptoms become mild or go away within 14 to 23 days on average compared to 29 days for those who received placebo.

To learn this, researchers tracked the severity of participants' COVID-19 symptoms for 29 days after they received trial treatment. They measured how long it took for the participants' COVID-19 symptoms to become mild or go away completely.

What medical problems did the participants have during the trial?

Medical problems that happen in clinical trials are called "**adverse events**".

A lot of research is needed to know whether a drug causes an adverse event. So, when new drugs are being studied, researchers keep track of all adverse events the participants have, whether or not they are thought to be caused by the trial treatment.

This section is a summary of the adverse events that happened up to about 3 months after the trial treatment. The websites listed at the end of this summary have more information about the adverse events that happened in this trial.

An **adverse event** is any sign or symptom that participants have during a trial. An adverse event is considered "**serious**" when it is life-threatening, causes lasting problems, or the participant needs hospital care. These problems may or may not be caused by the trial treatment.

How many participants had adverse events?

	High dose MP0420 100 participants	Medium dose MP0420 98 participants	Low dose MP0420 102 participants	Placebo 100 participants
Participants who had at least 1 adverse event	**51** of 100 51%	**42** of 98 43%	**40** of 102 39%	**54** of 100 54%
Participants who had at least 1 serious adverse event	**0** of 100 0%	**2** of 98 2%	**1** of 102 1%	**9** of 100 9%
Participants who stopped receiving the trial drug due to an adverse event	**0** of 100 0%	**0** of 98 0%	**1** of 102 1%	**0** of 100 0%
Deaths	**0** of 100 0%	**0** of 98 0%	**0** of 102 0%	**2** of 100 2%

What were the serious adverse events?

2 participants in the placebo group died due to COVID-19 pneumonia (lung infection caused by COVID-19).

12 participants had serious adverse events. The table below shows the **most common serious adverse events** that happened in 2 or more participants (2% or more) in any group:

	High dose MP0420 100 participants	Medium dose MP0420 98 participants	Low dose MP0420 102 participants	Placebo 100 participants
Lung infection caused by COVID-19 COVID-19 pneumonia	**0** of 100 0%	**1** of 98 1%	**0** of 102 0%	**4** of 100 4%
Life-threatening drop in blood pressure during an infection Septic shock	**0** of 100 0%	**0** of 98 0%	**0** of 102 0%	**2** of 100 2%

What were the most common non-serious adverse events?

184 participants had adverse events that were not considered serious.

The table below shows the **non-serious adverse events** that happened in 6 or more participants (6% or more) in any group:

	High dose MP0420 100 participants	Medium dose MP0420 98 participants	Low dose MP0420 102 participants	Placebo 100 participants
Possible sign that the kidneys are not working well Blood creatinine increased	**6** of 100 6%	**4** of 98 4%	**3** of 102 3%	**6** of 100 6%
Possible sign of liver damage Alanine aminotransferase increased	**7** of 100 7%	**3** of 98 3%	**1** of 102 1%	**2** of 100 2%
Possible sign of liver damage Aspartate aminotransferase increased	**6** of 100 6%	**3** of 98 3%	**1** of 102 1%	**2** of 100 2%
COVID-19 that got worse COVID-19	**6** of 100 6%	**2** of 98 2%	**1** of 102 1%	**4** of 100 4%
Possible sign of pancreas damage Lipase increased	**6** of 100 6%	**0** of 98 0%	**3** of 102 3%	**1** of 100 %

How has this trial helped?

This trial helped researchers learn how well MP0420 works and if it is safe to use in people with mild to moderate COVID-19. The trial ended early because treatments for COVID-19 became available during this trial. When this summary was written, there were no plans for future trials to study MP0420 in people with COVID-19.

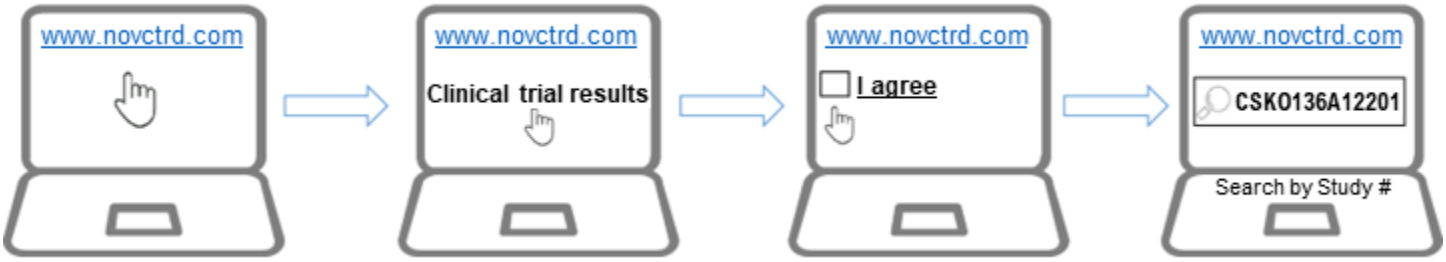
The researchers concluded that, compared to those who received the placebo, participants who received any dose of MP0420:

- Had less virus in their bodies
- Were less likely to receive hospital or ER care for COVID-19 or die
- Had their COVID-19 symptoms become mild or go away sooner

Where can I learn more about this trial?

More information about the results and adverse events in this trial can be found in the scientific summary of the results available on the Novartis Clinical Trial Results website (www.novctrd.com).

Follow these steps to find the scientific summary:



You can find more information about this trial on these websites:

- www.clinicaltrials.gov. Use the NCT identifier **NCT04828161** in the search field.
- www.clinicaltrialsregister.eu. Use the EudraCT identifier **2021-000890-10** in the search field.

Full clinical trial title: A Randomized, Double-blind, Placebo-controlled, Multicenter Study of Ensovibep (MP0420) in Ambulatory Adult Patients with Symptomatic COVID-19 – The "EMPATHY" Trial

Thank you

Thank you for taking part in this trial. As a clinical trial participant, you belong to a large community of participants around the world. You helped researchers answer important health questions and test new medical treatments.

NOVARTIS

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