

# Clinical Trial Results Summary

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A clinical trial to learn about the effects and safety of MHV370 in people with Sjögren's syndrome or mixed connective tissue disease

## Thank you!

Thank you to the participants who took part in the clinical trial for Sjögren's syndrome (SjS), also known as Sjögren's disease, and mixed connective tissue disease (MCTD). Every participant helped the researchers learn about the trial drug **MHV370**.

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:** CMHV370A12201

**Drug studied:** MHV370

**Sponsor:** Novartis

..... 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.

# What was the main purpose of this trial?

The purpose of this trial was to learn about the effects and safety of the trial drug MHV370 for people with Sjögren's syndrome or mixed connective tissue disease.



**Sjögren's syndrome (SjS)** is an **autoimmune disease** where the body attacks and damages the glands that make fluid, like tears and saliva. People with SjS have dry eyes and dry mouth. They also have pain and fatigue that affect their daily lives. SjS can cause more serious health problems, such as infections, cancer, and kidney or liver problems.

## What is an autoimmune disease?

An autoimmune disease means the immune system attacks healthy cells by mistake.



**Mixed connective tissue disease (MCTD)** is an autoimmune disease that can cause many different symptoms that may change over time. People with MCTD may feel tired and have trouble breathing, swollen hands, muscle or joint pain, and numb fingers or toes.



**MHV370** is a trial drug designed to lower the activity of certain cells in the immune system. Researchers think these immune cells may play a role in SjS and MCTD.



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

- Did participants have less severe SjS or MCTD symptoms after taking MHV370?
- What adverse events did the participants have during this trial?
  - ↳ An **adverse event** is any sign or symptom that participants have during a trial.

# How long was this trial?



The trial began in November 2021 and ended in March 2023.

The sponsor paused the trial in September 2022 to do a safety review. After reviewing the data, the sponsor concluded there was no safety concern.

During the pause, the sponsor decided to stop the trial early in February 2023. The decision to stop early was not related to the safety of the trial drug.

# Who was in this trial?

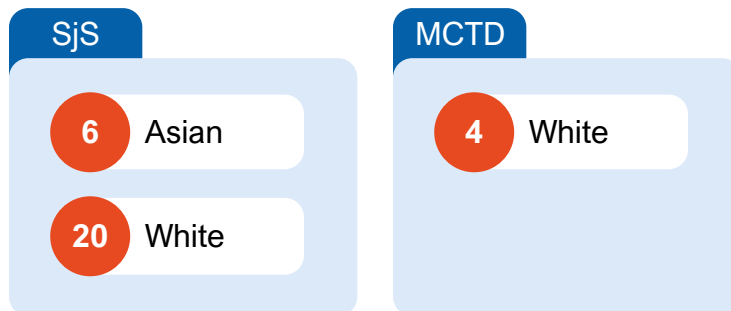


30 participants received treatment in this trial – 26 with SjS and 4 with MCTD. All of them were women.

In participants with SjS, their ages ranged from 28 to 67 years. Their average age was 52 years.

In participants with MCTD, their ages ranged from 26 to 44 years. Their average age was 40 years.

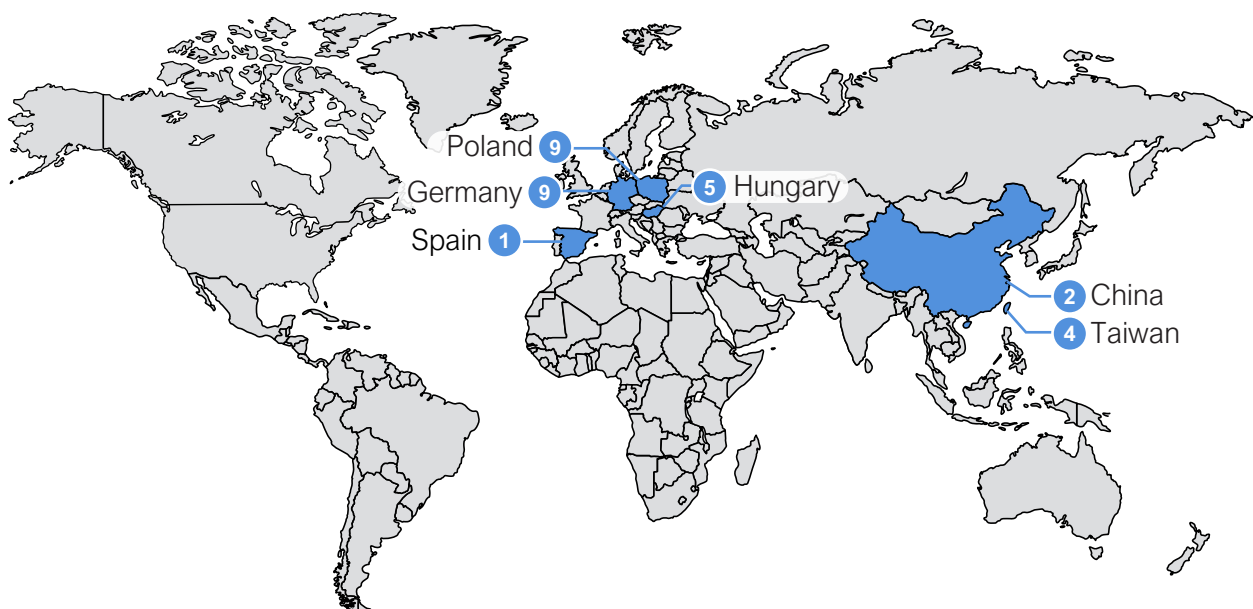
The number of participants by race is shown below.



The participants could take part in this trial if they:

- Had received all COVID-19 vaccine doses and boosters as required by their country
- Had not recently received certain treatments that affect the immune system within 6 months of joining the trial

30 participants from 6 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:



**MHV370:** 200 milligrams (mg)



**Placebo** looks like the trial drug but does not have any trial drug in it. Using a placebo helps researchers better understand the effect of a trial drug.

The participants took their assigned treatment by mouth as capsules 2 times a day.

Researchers randomly assigned participants to one of the treatments above using a computer.

None of the participants, researchers, and trial staff knew what treatment the participants were taking. Some trials are done this way because knowing what treatment the participants take 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.

Along with the treatments above, participants could take other treatments for their SjS or MCTD.

## What happened during this trial?

### Before treatment

Up to 6 weeks



Trial doctors checked the participants' health and SjS or MCTD to make sure they could be in this trial.

### During treatment

Up to 6 months



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

  
26 participants  
with **SjS**

12 participants took **MHV370**  
as capsules 2 times a day

14 participants took the **placebo**  
as capsules 2 times a day

  
4 participants  
with **MCTD**

2 participants took **MHV370**  
as capsules 2 times a day

2 participants took the **placebo**  
as capsules 2 times a day

### After treatment

About 1 month



Participants returned to their trial site about 1 month after receiving their last dose of treatment to have their general health checked.

## What were the main results of this trial?

### Did participants have less severe SjS or MCTD symptoms after taking MHV370?



Because the trial ended early, researchers could not conclude if participants who took MHV370 had less severe SjS or MCTD symptoms compared to those who took placebo.

To find this out, researchers measured how severe the participants' symptoms were using one of these measures:

- EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI) for participants with SjS. ESSDAI is a tool that doctors use to measure the effect of SjS on the body.
- Physician Global Assessment (PhGA) for participants with MCTD. PhGA is a scale that doctors use to measure the severity of different diseases, including MCTD, during a physical exam.

Researchers planned to compare the change in participants' ESSDAI or PhGA scores from before treatment to after 6 months of treatment.

## What were the other results of this trial?

### Did MHV370 change other measures of SjS and MCTD?



Because the trial ended early, the researchers could not conclude if MHV370 changed other measures of SjS and MCTD compared to placebo.

To find this out, the researchers also planned to compare changes over time in these measures:

- The severity of signs and symptoms of SjS and MCTD using different measures
- How much saliva and tears participants with SjS could make
- How easily participants with MCTD could breathe, how well their lungs worked, and whether lung problems affected their daily lives
- Raynaud's syndrome symptoms for participants with MCTD. **Raynaud's syndrome** causes the fingers or toes to feel numb and change color to white or purple

# What adverse events did the participants have?

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.

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

This section is a summary of the adverse events that happened until about 1 month after the last dose of trial treatment.

An **adverse event** is:

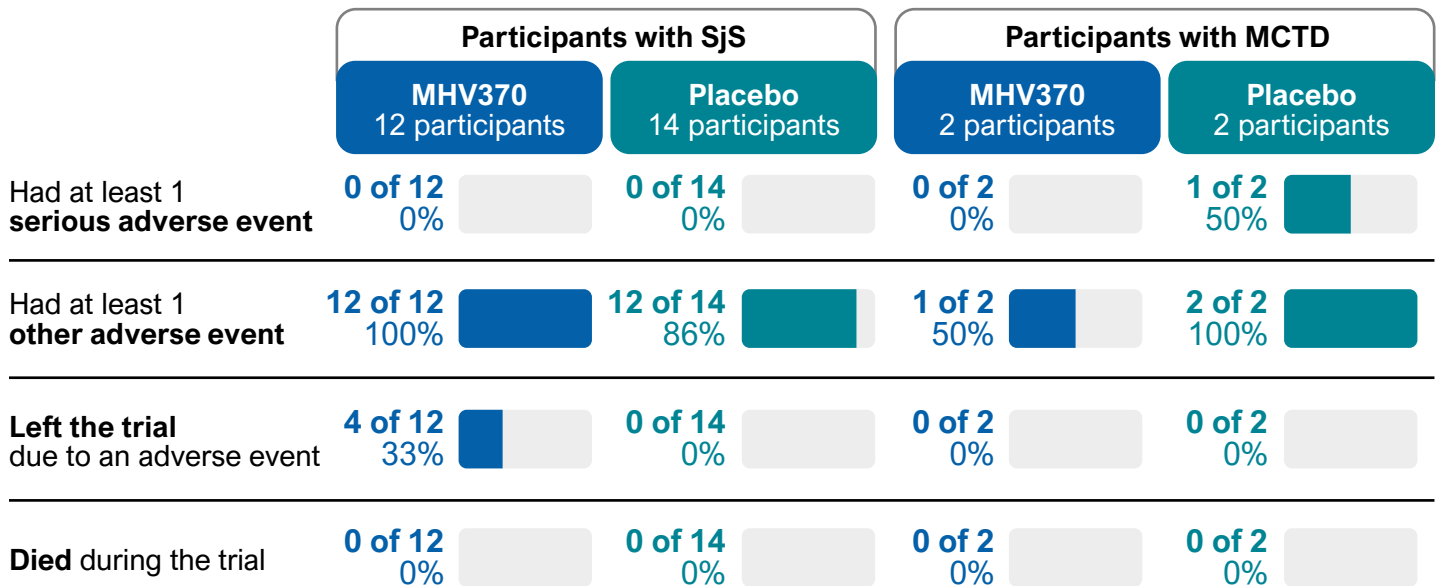
- Any **sign or symptom** that the participants have during a trial
- Considered **serious** when it is life-threatening, causes lasting problems, the participant needs hospital care, or results in death

Adverse events **may** or **may not** be caused by treatments in the trial.



Almost all the participants (27 of 30) had adverse events. 1 participant had an adverse event that was considered serious. 4 participants left the trial due to an adverse event. The researchers concluded there were no safety concerns for MHV370 in this trial.

## How many participants had adverse events?



# What serious adverse events did the participants have?

No participants died. 1 participant with MCTD who took the placebo had a serious adverse event:

- A fluid-filled sac on or inside the ovary | Ovarian cyst

# What other adverse events did the participants have?

27 participants had other adverse events.

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

	Participants with SjS		Participants with MCTD	
	MHV370 12 participants	Placebo 14 participants	MHV370 2 participants	Placebo 2 participants
COVID-19	4 of 12 33% <div><div></div></div>	2 of 14 14% <div><div></div></div>	0 of 2 0% <div><div></div></div>	0 of 2 0% <div><div></div></div>
Headache	2 of 12 17% <div><div></div></div>	4 of 14 29% <div><div></div></div>	0 of 2 0% <div><div></div></div>	2 of 2 100% <div><div></div></div>
Throat pain Oropharyngeal pain	3 of 12 25% <div><div></div></div>	2 of 14 14% <div><div></div></div>	0 of 2 0% <div><div></div></div>	0 of 2 0% <div><div></div></div>

# What was learned from this trial?

Researchers wanted to learn about the effects and safety of MHV370 for participants with SjS or MCTD.



Because the trial ended early, researchers could not conclude if participants had less severe SjS or MCTD symptoms after taking MHV370. The researchers concluded there were no safety concerns for MHV370 in this trial.

Researchers look at the results of many trials to learn about the safety and effects of new treatments.

There are other trials planned for MHV370 in SjS or MCTD.

# 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](http://www.novctrd.com)

Follow these steps to find the scientific summary:



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

- [clinicaltrials.gov](http://clinicaltrials.gov) – search using the number **NCT04988087**
- [clinicaltrialsregister.eu/ctr-search/search](http://clinicaltrialsregister.eu/ctr-search/search) – search using the number **2020-004937-19**

If more trials are planned, they will appear on the public websites above. When there, search for **MHV370, Sjögren's disease, Sjögren's syndrome, SjD, SjS, Mixed connective tissue disease, or MCTD.**

**Full clinical trial title:** A multi-center, randomized, participant- and investigator- blinded, placebo-controlled, parallel group basket study to evaluate the safety, tolerability and efficacy of MHV370 in participants with Sjögren's Syndrome or Mixed Connective Tissue Disease



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

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