NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about the safety of MHS552 in people with systemic lupus erythematosus

Thank you!

Thank you to the participants who took part in the clinical trial for **systemic lupus erythematosus (SLE)**. Every participant helped the researchers learn more about the trial drug **MHS552**.

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: CMHS552D12101
Novartis drug studied: MHS552
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 results.

What was the main purpose of this trial?

The purpose of this trial was to learn more about the safety of different dose levels of MHS552 in people with systemic lupus erythematosus (SLE). This type of trial helps researchers know what other trials may be needed and what doses to use in the future.

Systemic lupus erythematosus or **SLE** is the most common type of lupus. SLE is an autoimmune disease, which means the immune system attacks healthy cells in the body by mistake. The **immune system** is made up of cells and proteins that help the body fight off infections or other possible harms.

In SLE, the immune system causes inflammation and tissue damage throughout the body, especially in the skin, joints, and kidneys. Depending on the cells attacked, it may cause many different symptoms that range from mild to life-threatening.

What is inflammation?

Inflammation is one of the ways the immune system protects the body from disease and infection. However, too much inflammation can be harmful.

MHS552 is a trial drug designed to raise the level of certain cells in the immune system. Researchers think this may control and prevent the immune system from attacking healthy cells. This trial did **not** look at the impact of MHS552 on SLE.

The trial's purpose was to answer this main question:

- What medical problems, also called 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 March 2022 and ended in June 2023.

In June 2023, the trial ended early because sponsor decided to stop further research on MHS552. This was a business decision and not related to the safety of the trial drug.

This trial was planned to have 2 Parts:

- **Part A** was planned to look at the safety of different dose levels of MHS552 when given weekly for 4 weeks. Because the trial ended early, researchers only assigned participants to 2 dose levels.
- **Part B** was planned to look at the safety of MHS552 when received for 3 months, but never started.

Who was in this trial?

8 participants with SLE received treatment in this trial – 1 man and 7 women. Participants' ages ranged from 29 to 63 years. Their average age was 47 years. The number of participants by race is shown below.

Race

1 Asian	1 Black or African American	6 White

The participants could take part in this trial if they:

- Had mild or moderately active SLE
- Were taking at least one medicine for their SLE, such as steroids
- Did not have other types of lupus or certain other autoimmune diseases

This trial took place in Germany.

What treatments did the participants receive?

The treatments in Part A of this trial were:

MHS552 - given as an injection under the skin once a week for about 1 month. This trial looked at 2 dose levels of MHS552:

- **Lower dose:** 1 milligram (mg)
- **Higher dose:** 3 mg

Placebo - given as an injection under the skin once a week for about 1 month. A 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.

Researchers randomly assigned participants to treatment groups using a computer. Participants were assigned to receive one of the treatments listed above.

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.

All participants continued taking certain medicines for SLE.

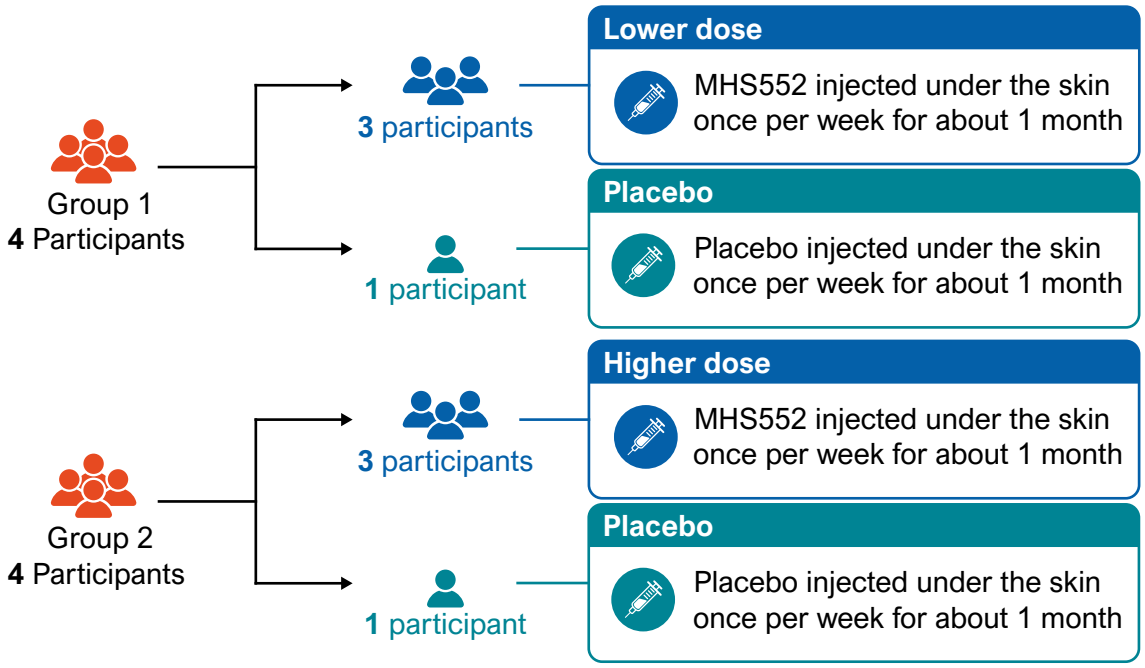
What happened during this trial?

Before treatment — About 6 weeks

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

During treatment — About 1 month

Participants received treatment in one of these groups in Part A:



Trial staff checked the participants' health and took blood samples throughout the trial.

After treatment — Up to about 3 months

Participants returned to their trial site 3 times after treatment for follow-up visits to check their health. Women who could get pregnant had another follow-up 3 months after receiving their last dose of trial treatment.

What were the main results of this trial?

What medical problems, also called adverse events, did the participants have during this trial?

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 from first trial treatment up to 3 months 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 participants (7 of 8) had at least one adverse event. A similar number of participants in both MHS552 groups had adverse events. None of the participants had adverse events which were considered serious. 1 participant who received MHS552 and 1 participant who received placebo stopped treatment due to an adverse event. No participants left the trial due to an adverse event. The researchers concluded there were no new safety concerns for MHS552 in this trial.

How many participants had adverse events?

Participants who:	MHS552 (both doses) 6 participants	Placebo 2 participants
Had at least 1 **serious adverse event**	**0 of 6** 0%	**0 of 2** 0%
Had at least 1 **other adverse event**	**5 of 6** 83%	**2 of 2** 100%
Stopped receiving trial treatment due to an adverse event	**1 of 6** 17%	**1 of 2** 0%
Left the trial due to an adverse event	**0 of 6** 0%	**0 of 2** 0%
Died during the trial	**0 of 6** 0%	**0 of 2** 0%

What serious adverse events did the participants have?

No participants had serious adverse events, including no deaths.

What other adverse events did the participants have?

7 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.

	MHS552 (both doses) 6 participants	**Placebo** 2 participants
Swelling, itching, or pain at the injection site Injection site reaction	**3 of 6** 50%	**0 of 2** 0%
Redness at the injection site Injection site erythema	**2 of 6** 33%	**0 of 2** 0%
Headache	**2 of 6** 33%	**1 of 2** 50%
COVID-19	**2 of 6** 33%	**0 of 2** 0%

What were the other results of this trial?

How much and how fast did MHS552 get into the participants' blood?

The researchers found that:

- For most participants who received the **lower dose** of **MHS552**, the amount of MHS552 in their blood was too low to measure
- For participants who received the **higher dose** of **MHS552**, it reached peak level about 1 day after treatment

To learn this, the trial staff took many blood samples from each participant after they received MHS552. They measured the amount of MHS552 in the participants' blood over time.

What was learned from this trial?

Researchers learned about the safety of different dose levels of MHS552 in people with SLE. In June 2023, the trial ended early because the sponsor decided to stop research on MHS552.

The researchers concluded that:

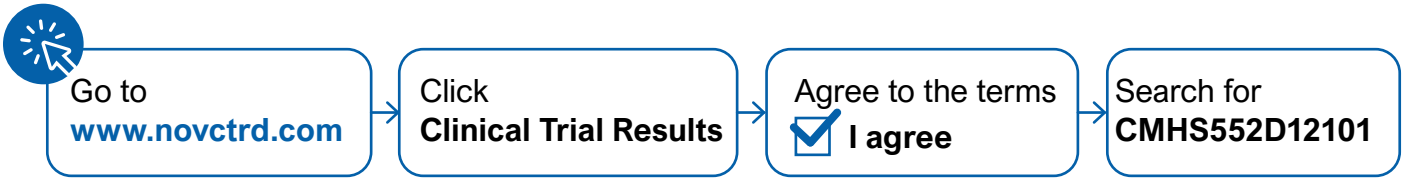
- There were no new safety concerns for either dose of MHS552 in this trial
- For most participants, the total amount of MHS552 in their blood was too low to measure
- For participants with enough MHS552 in their blood to measure, MHS552 reached peak level about 1 day after treatment

When this summary was written, the sponsor had no plans for other trials with MHS552.

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:



For more information about this trial, go to this website:

- clinicaltrials.gov – search using the number **NCT05203419**

Full clinical trial title: A two-part, randomized, investigator- and participant- blinded, placebo-controlled, multiple ascending dose study to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of MHS552 in adult participants with Systemic Lupus Erythematosus (SLE)

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