NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about the safety and effects of MBL949 in people living with obesity

Thank you!

Thank you to the participants who took part in the clinical trial for people living with **obesity**, with or without type 2 diabetes. Every participant helped the researchers learn more about the trial drug **MBL949**.

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: CMBL949A12201
Novartis drug studied: MBL949
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 the trial was to learn about the safety and effects of MBL949 in people living with obesity, with or without type 2 diabetes.

Obesity means a person has too much body fat. Obesity raises a person's chance of having other serious health problems, including type 2 diabetes.

Type 2 diabetes is a disease in which the body doesn't use sugar the way it should. It causes high blood sugar levels, which can lead to serious health problems over time, such as kidney damage, nerve damage, and heart disease.

MBL949 is a trial drug designed to lower a person's weight by making them feel less hungry.

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

- What adverse events did the participants have?
  - ↳ An **adverse event** is any sign or symptom that participants have during a trial.
- Did the participants lose weight after receiving MBL949?

How long was this trial?

The trial began in February 2022 and ended in May 2023.

In May 2023 the researchers decided to stop this trial early. The trial sponsor reviewed the data and decided MBL949 did not have enough of an effect on weight loss given the number of adverse events. Because of this, the sponsor decided not to continue studying MBL949 in obesity. The decision to stop was not related to the safety of MBL949.

Who was in this trial?

126 participants living with obesity received treatment in this trial.
12 participants also had type 2 diabetes.
There were 25 men and 101 women.

Participants' ages ranged from 21 to 60 years. Their average age was 45 years.

The number of participants by race are shown below.

Race

29 Black or African American	97 White

The participants could take part in this trial if they:

- Had a body mass index, also called BMI, that showed they were living with obesity. **BMI** is a measure based on someone's weight and height.
- Weighed at least 170 pounds

This trial took place in the United States.

What treatments did the participants receive?

The treatments in this trial were:

MBL949 – given as injections under the skin at dose levels that ranged from 1.5 to 12 milligrams (mg)

Placebo – given as injections under the skin. 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.

The treatments were given every 2 weeks. Researchers randomly assigned participants to treatment groups using a computer.

None of the participants, researchers, 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.

During the trial, participants could continue taking certain medicines for type 2 diabetes.

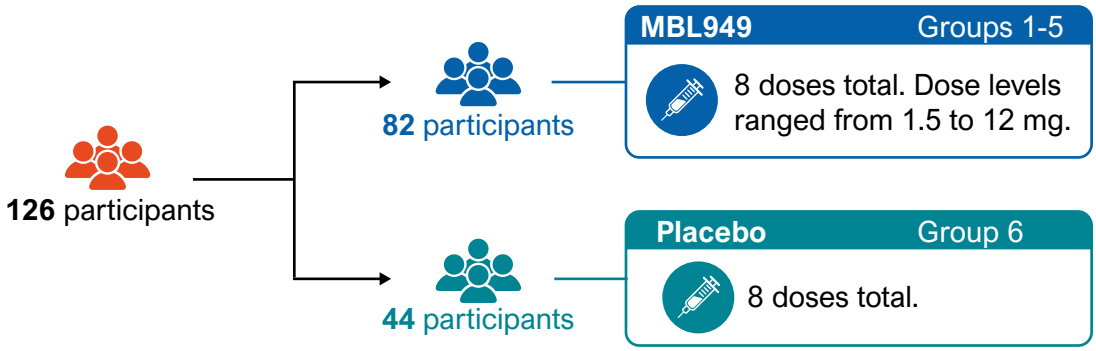
What happened during this trial?

Before treatment — About 1 month

Trial staff checked the participants' health, weight, and blood sugar levels to make sure they could be in this clinical trial.

During treatment — About 3 months

Participants received a dose of either MBL949 or the placebo every 2 weeks. They received 8 doses in total. Participants were assigned to 1 of 6 groups. Groups 1 through 5 each received more than one dose level of MBL949. The graphic below shows how many participants were assigned to MBL949 or the placebo.



Trial staff checked the participants' health and weight throughout the trial.

After treatment — About 2 months

Participants returned to their trial site up to 7 times after receiving their last dose of treatment. During these visits, the trial staff checked the participants' health and weight.

What were the main results of this trial?

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 after participants received their first dose of trial treatment up to about 2 months after their last dose.

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.

Most of the participants (100 of 126) had adverse events. No participants had adverse events that were considered serious. The most common adverse event was feeling sick to the stomach. 5 participants left the trial due to an adverse event. The researchers concluded there were no new safety concerns for MBL949 in this trial.

How many participants had adverse events?

Participants who:	**MBL949** (all groups) 82 participants	**Placebo** 44 participants
Had at least 1 **serious adverse event**	**0 of 82** 0%	**0 of 44** 0%
Had at least 1 **other adverse event**	**70 of 82** 85%	**30 of 44** 68%
Left the trial due to an adverse event	**5 of 82** 6%	**0 of 44** 0%
Died during the trial	**0 of 82** 0%	**0 of 44** 0%

What serious adverse events did the participants have?

None of the participants had serious adverse events, including no deaths.

What other adverse events did the participants have?

100 participants had other adverse events.

The table below shows the other adverse events that happened in **12 or more** of all participants. Additional adverse events happened in fewer participants.

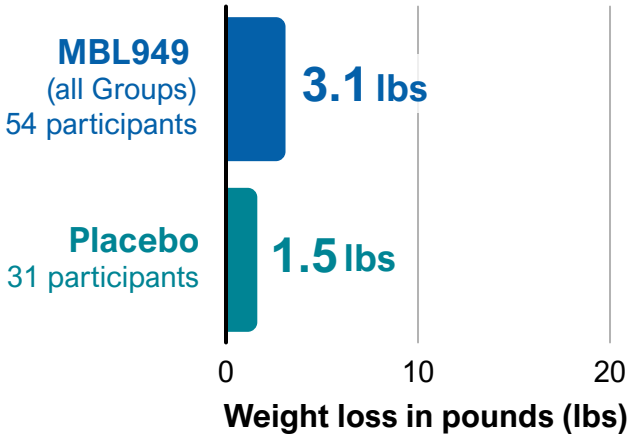
	MBL949 (all groups) 82 participants	**Placebo** 44 participants
Feeling sick to the stomach Nausea	**58 of 82** 71%	**17 of 44** 39%
Throwing up Vomiting	**32 of 82** 39%	**3 of 44** 7%
Trouble passing stool Constipation	**16 of 82** 20%	**2 of 44** 5%
Headache	**14 of 82** 17%	**1 of 44** 2%
COVID-19	**6 of 82** 7%	**6 of 44** 14%

Did the participants lose weight after receiving MBL949?

There was a small amount of weight loss after receiving MBL949 for about 3 months. The average weight loss was about 3 pounds. Overall, researchers concluded MBL949 did not have enough of an effect on weight loss given the number of adverse events.

To learn this, researchers measured each participant's weight before they started trial treatment and many times during trial treatment. They compared the average weight change of participants who received MBL949 to those who received placebo.

Average weight loss in all participants after about 3 months of treatment



This graph only includes participants who had their weight measured before and after about 3 months of treatment.

What was learned from this trial?

Researchers learned about the safety and effects of MBL949 in people living with obesity, with or without type 2 diabetes. The trial ended early because they reviewed the data and decided not to continue studying MBL949 in obesity.

The researchers concluded that:

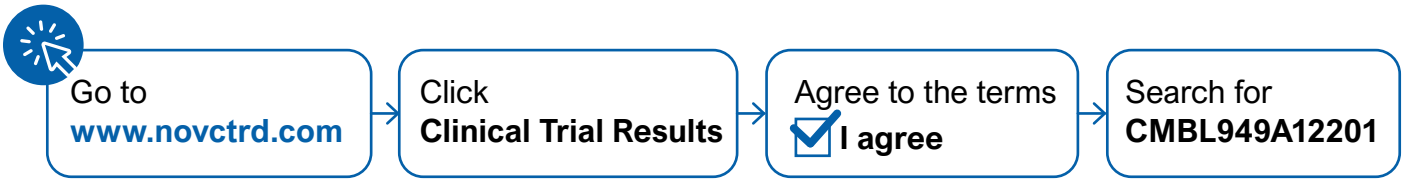
- There were no new safety concerns for MBL949 in this trial
- Overall, MBL9494 did not have enough of an effect on weight loss given the number of adverse events

When this summary was written, the sponsor had no plans for future trials of MBL949 in people living with obesity, with or without type 2 diabetes.

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 any of these websites:

- **clinicaltrials.gov** – search using the number **NCT05199090**
- **clinicaltrialsregister.eu/ctr-search/search** – search using the number **2021-004449-19**

Full clinical trial title: A randomized, placebo-controlled, participant-and-investigator-blinded, sponsor open-label study to evaluate the safety, tolerability, and efficacy with different dosing regimens of subcutaneously administered MBL949 in obese participants with or without type 2 diabetes mellitus

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