NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about the effects of ofatumumab on immune response to COVID-19 vaccine in people with multiple sclerosis

Thank you!

Thank you to the participants who took part in this clinical trial looking at the COVID-19 vaccine response in people with **multiple sclerosis** taking **ofatumumab**. Every participant helped the researchers learn more about the trial drug **ofatumumab**, also called **OMB157**.

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: COMB157GUS16
Drug studied: OMB157, also known as ofatumumab
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.

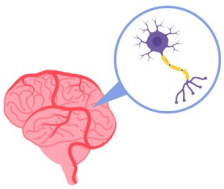
This summary shows the results of a single clinical trial. Other clinical trials may have different findings.

What was the main purpose of this trial?

The purpose of this trial was to learn more about the effects of **ofatumumab** on the **immune response** to the COVID-19 vaccine in people with **multiple sclerosis**.

An **immune response** is how the body identifies and protects itself from bacteria, viruses, and other harmful substances.

Researchers compared the immune responses of participants who received **ofatumumab** with those who received **other MS treatments**.



Multiple Sclerosis (**MS**) is a condition that affects the brain and spinal cord. In MS, the body's immune system attacks and damages the protective coating around the nerves, called myelin. This leads to nerve damage and scar tissue formation, causing various symptoms.

People with **relapsing MS** can experience new symptoms that can be temporary or permanent.

This trial included people with **relapsing MS**.

Ofatumumab is an approved treatment for relapsing MS. It targets the immune system which may lead to a reduced immune response to vaccines.

Trial drug
ofatumumab
Pronounced as
OH-fa-TOO-moo-mab

Other MS treatments included different types of drugs collectively called injectable disease-modifying therapies which were not expected to affect the body's immune response to vaccines.

Participants in this study could have been receiving either interferon or glatiramer acetate as other MS treatments.

COVID-19 vaccine helps prevent severe illness due to COVID-19. This trial studied the immune response to a type of COVID-19 vaccine called messenger ribonucleic acid (mRNA) vaccine. Such vaccines do not use live viruses, but a molecule called mRNA which helps trigger an immune response inside the body.

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

- How many participants treated with **ofatumumab** had an immune response to the COVID-19 vaccine 14 days after full vaccination?
- What adverse events did the participants have during this trial?

  An **adverse event** is any sign or symptom that participants have during a trial. It **may** or **may not** be caused by treatments in the trial.

How long was this trial?

The trial began in June 2021 and ended earlier than expected in April 2023. Each participant was in the trial for a maximum of 1 year and 2 months.

The sponsor stopped the trial early due to fewer participants joining the trial than planned.

Who was in this trial?

24 participants with **multiple sclerosis** (**MS**) joined this trial in the United States. Participants' ages ranged from 25 to 55 years.

The number of participants by gender and race are shown below.

Gender

5 Men	19 Women

Race

20 White	3 Black or African American	1 Not reported

The participants could take part in this trial if they:

- were between 18 and 55 years of age
- were diagnosed with **relapsing MS**
- were planning to start **ofatumumab**, or were already receiving **ofatumumab** or **other MS treatments**
- were planning to receive or had received the full course (2 doses) of COVID-19 mRNA vaccine*

*Participants who were already fully vaccinated may or may not have received at least 1 booster dose of the COVID-19 vaccine.

What treatments did the participants receive?

Participants received either of the following treatments:

Ofatumumab: 20 milligrams given as an injection under the skin. Participants who started it in this trial received 3 weekly doses first, followed by monthly doses.

Other MS treatments: Interferon or glatiramer acetate were given as an injection under the skin or into a muscle.

Participants who were already receiving **ofatumumab** or **other MS treatments** before joining the trial continued taking them as prescribed to them by their regular doctors.

In addition, participants received or had already received the full course of COVID-19 vaccine from their healthcare provider outside of the trial. It was given as an injection into a muscle.

In this trial, the participants and trial staff knew what treatment each participant received.

What happened during this trial?

Before treatment

Up to 7 days

Trial doctors checked the participants' health to ensure they could take part in this clinical trial.

During treatment

Up to 1 year and 1 month

The participants were divided into the following groups depending on the timing of the COVID-19 vaccination and their **multiple sclerosis** (**MS**) treatment:

	Fully vaccinated	Treatment
Group 1 5 participants	After joining the trial	Started receiving **ofatumumab** weekly after 2 weeks of being fully vaccinated and then took it monthly
Group 2 2 participants	After joining the trial	Were already receiving **ofatumumab** for at least 4 weeks before joining the trial and continued as prescribed
Group 3 No participant was assigned	After joining the trial	Were already receiving **other MS treatments** for at least 4 weeks before joining the trial and continued as prescribed
Group 4 1 participant	Before joining the trial	Were already receiving **ofatumumab** for at least 4 weeks before joining the trial and continued as prescribed
Group 5 11 participants	Before joining the trial (with or without a booster dose)	Were already receiving **other MS treatments** for at least 4 weeks before joining the trial and continued as prescribed
Group 6 5 participants	Before joining the trial (with a booster dose)	Were already receiving **ofatumumab** for at least 4 weeks before joining the trial and continued as prescribed

After treatment Up to 1 month

A month after receiving their last treatment, participants returned to the trial site or were contacted by trial doctors or staff for a health check-up.

What was the main result of this trial?

How many participants treated with ofatumumab showed an immune response to the COVID-19 vaccine 14 days after full vaccination?

The majority of participants treated with **ofatumumab** (9 out of 12) and participants receiving **other MS treatments** (10 out of 10) had an immune response to the COVID-19 vaccine 14 days after full vaccination.

Of the 24 participants who joined this trial, 2 were excluded (one from **Group 5** and one from **Group 6**) from the following results because they were diagnosed with COVID-19 before starting the trial.

To answer this question, researchers collected blood samples from the participants at certain times and checked whether they had antibodies against the virus that causes COVID-19.

Number (percentage) of participants who had an immune response to COVID-19 vaccine

Group 1 5 participants	Group 2 2 participants	Group 4 1 participant	Group 5 10 participants	Group 6 4 participants
Fully vaccinated during the trial and started **ofatumumab** in the trial	Fully vaccinated during the trial and were receiving **ofatumumab** before joining the trial	Fully vaccinated before joining the trial and were receiving **ofatumumab** before joining the trial	Fully vaccinated (with or without a booster) and were receiving **other MS treatments** before joining the trial	Fully vaccinated with a booster dose and were receiving **ofatumumab** before joining the trial
5 of 5 (100%)	**2 of 2** (100%)	**0 of 1**	**10 of 10** (100%)	**2 of 4** (50%)

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 from the start of treatment up to 1 month after the 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.

Note: Researchers planned to combine the adverse events for **Group 2** and **Group 4** as the participants in both groups were already receiving **ofatumumab** before being fully vaccinated. Similarly, the adverse events were combined for **Group 3** and **Group 5**, as the participants were already receiving **other MS treatments** before being fully vaccinated. However, there were no participants assigned to **Group 3**.

10 of 24 participants had adverse events. 2 participants had adverse events that were considered serious. None of the participants died or left the trial due to an adverse event. Researchers concluded that there were no new safety concerns with the use of **ofatumumab** during this trial.

How many participants had adverse events?

Participants who:	Group 1 5 participants Were fully vaccinated during the trial and started **ofatumumab** in the trial	Group 2 and 4 3 participants Were fully vaccinated before or during the trial and were receiving **ofatumumab** before joining the trial	Group 5 11 participants Were fully vaccinated (with or without a booster) and were receiving **other MS treatments** before joining the trial	Group 6 5 participants Were fully vaccinated with a booster dose and were receiving **ofatumumab** before joining the trial
Had at least 1 serious adverse event	0	0	1 of 11 9%	1 of 5 20%
Had at least 1 other adverse event	5 of 5 100%	1 of 3 33%	2 of 11 18%	2 of 5 40%

What serious adverse events did the participants have?

2 participants had serious adverse events:

- 1 participant in **Group 5** had a **blood clot in a large vein located deep in the body** (deep vein thrombosis)
- 1 participant in **Group 6** had a **foot fracture**

What other adverse events did the participants have?

10 participants had other adverse events.

The table below shows the other adverse events that happened in **30%** or more participants in any group during the trial:

	Group 1 5 participants	Group 2 and 4 3 participants	Group 3 and 5 11 participants	Group 6 5 participants
A spinning sensation Vertigo	0	1 of 3 33%	0	0
Feeling sick Nausea	2 of 5 40%	0	0	0
Chills	2 of 5 40%	0	0	0
Feeling tired Fatigue	0	1 of 3 33%	0	0

	Group 1 5 participants	Group 2 and 4 3 participants	Group 3 and 5 11 participants	Group 6 5 participants
Pain	**2 of 5** 40% 	0	0	0
Urinary tract infection	0	0	0	**2 of 5** 40% 
High blood pressure Blood pressure increased	0	**1 of 3** 33% 	0	0
Joint pain Arthralgia	0	**1 of 3** 33% 	0	0
Discomfort in arms or legs Limb discomfort	0	**1 of 3** 33% 	0	0
Discomfort in the muscles Muscles discomfort	0	**1 of 3** 33% 	0	0
Discomfort in the muscles and the bones Musculoskeletal discomfort	0	**1 of 3** 33% 	0	0
Muscle pain Myalgia	0	**1 of 3** 33% 	0	0
Pain in arms or legs Pain in extremity	0	**1 of 3** 33% 	0	0
Headache	**1 of 5** 20% 	**1 of 3** 33% 	0	0

What was learned from this trial?

Researchers learned more about the effects of **ofatumumab** on the immune response to COVID-19 vaccine in people with **multiple sclerosis** (**MS**).

The study was stopped early due to fewer participants joining the trial than planned.

The researchers concluded that:

- The majority of participants treated with **ofatumumab** (9 out of 12) and participants receiving **other MS treatments** (10 out of 10) had an immune response to COVID-19 vaccine at least 14 days after full vaccination
- There were no new safety concerns about **ofatumumab** during this trial

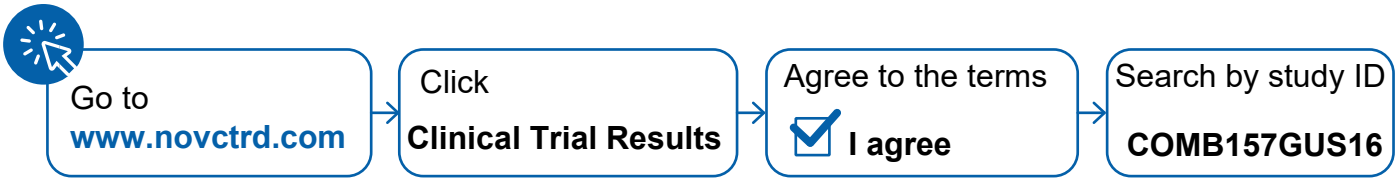
The findings from this trial may be useful to understand the benefits and risks of giving **ofatumumab** and the COVID-19 mRNA vaccine at the same time.

At the time of writing this summary, other trials with **ofatumumab** were ongoing.

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 the following website:

- www.clinicaltrials.gov - search using the number **NCT04878211**

If more trials are planned, they will appear on the public websites above.

When there, search for ofatumumab or COVID-19 vaccine.

Full clinical trial title An open-label multicenter study to assess response to COVID-19 vaccine in participants with multiple sclerosis treated with ofatumumab 20 mg subcutaneously

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