

Clinical Trial Results Summary

A clinical trial to learn more about the effects of ofatumumab in people with relapsing multiple sclerosis who were previously treated with a similar therapy

Thank you!

Thank you to the participants who took part in the clinical trial for **multiple sclerosis**. 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: COMB157GUS07

Novartis drug studied:
ofatumumab, also called **OMB157**

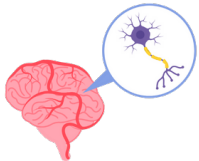
Sponsor: Novartis

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 effects of **ofatumumab** for people with **relapsing multiple sclerosis** who were previously treated with similar treatment as a drip into a vein (intravenous infusion). The participants had stopped their previous treatment for reasons other than safety or their treatment not working.



Multiple sclerosis (MS) is a condition that affects the brain and spinal cord. In people with **MS**, the immune system mistakenly attacks the protective coating around the nerves, called myelin. This leads to nerve damage and scar tissue formation or lesions, that can be seen on magnetic resonance imaging (MRI) scans and causes various **MS** symptoms.

Symptoms of **MS** can include tiredness, difficulty walking, numbness or tingling, muscle weakness, vision problems, and problems with coordination and balance. People with **relapsing MS** experience sudden new lesions or worsening symptoms of **MS** after a period of improvement.

Ofatumumab, also called **OMB157**, is an approved treatment for **relapsing MS**. In people with **MS**, certain types of white blood cells cause damage to the nervous system and lead to **MS** symptoms.

Ofatumumab works to reduce the number of these white blood cells.



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



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

- How many participants had the same or fewer active brain lesions on MRI scans after 1 year of treatment with **ofatumumab**?
- What medical problems, also called adverse events, happened during this trial?

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

How long was this trial?



The trial began in October 2020 and ended in October 2024. The participants were in the trial for at least 1 year and 2 months.

Who was in this trial?



102 participants with **relapsing MS** received treatment in this trial – 33 men and 69 women. Participants' ages ranged from 23 to 59 years. Their average age was 44 years.

The number of participants by race is shown below.



The participants could take part in this trial if they:

- were between 18 and 60 years old
- were diagnosed with **relapsing MS** and could at least walk without help
- had at least 2 courses of treatment with ocrelizumab or rituximab, with their last dose given 4 to 9 months before the trial
- stopped ocrelizumab or rituximab treatment for reasons other than safety or their treatment not working
- did not have any other ongoing immune system disease besides **relapsing MS**

All participants were from the United States.

What treatments did the participants receive?

The treatment in this trial was:



Ofatumumab at a dose of 20 milligrams, given as an injection under the skin. Everyone received one injection per week for the first 3 weeks and then one injection every month for a year, thereafter.

The participants, researchers, and trial staff knew that all participants were receiving **ofatumumab**.

What happened during the trial?

Before treatment

Up to 1 month



The trial staff checked to make sure the participants could be in this trial.

During treatment

Up to 1 year



102 participants received an initial injection of **ofatumumab** on Day 1, followed by an injection on Day 7, and Day 14. After that, they received one injection every month.

After treatment

Until the end of the trial



Trial staff checked participants' general health and for any medical problems for at least 1 month after participants' last dose of trial treatment.

After the trial, participants could continue **ofatumumab** or receive another **MS** treatment.

Participants had a month after completing the trial to start a new treatment. If they did not, they had check-ups every 3 months until they either began another treatment or their white blood cells returned to a healthy level.

Trial doctors checked participants for their overall health throughout the trial.

What were the main results of this trial?

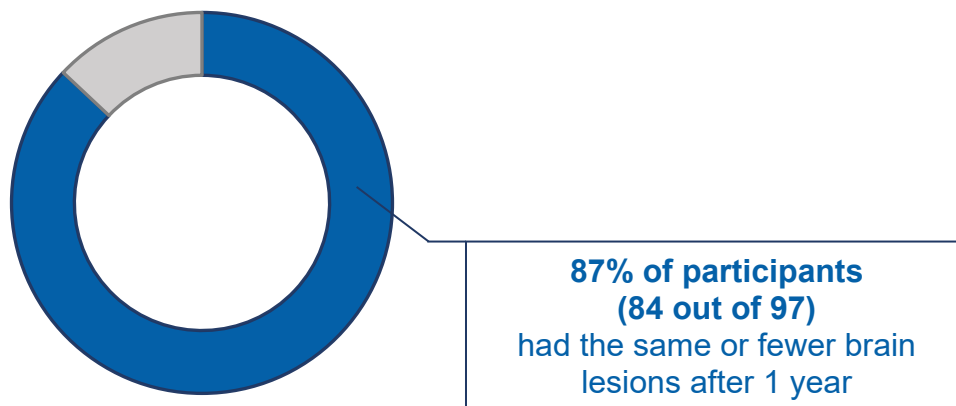
How many participants had the same or fewer active brain lesions on MRI scans after 1 year of treatment with **ofatumumab**?



Researchers concluded that overall participants had the same or fewer active brain lesions after 1 year of treatment with **ofatumumab**.

To answer this question, researchers performed MRI scans before and after 1 year of treatment to check for lesions in the brain due to **MS**. If a participant did not have a valid MRI scan after 1 year of treatment for whatever reason, researchers counted these participants as not responding to treatment (non-responder).

Out of the 97 participants who had available results, 84 had a valid brain MRI scan before the start of treatment and after 1 year of treatment. All 84 participants had the same or fewer active brain lesions on MRI scans after 1 year of treatment with **ofatumumab**.



What were the other results of this trial?

How many participants remained on **ofatumumab** treatment for at least 6 or 12 months?



Researchers found that **93%** of the participants (95 out of 102) remained on **ofatumumab** treatment for 6 months. At 12 months, **87%** of the participants (89 out of 102) were still taking **ofatumumab** treatment.

How satisfied were participants with how well **ofatumumab** worked, and how easy it was to use?

To answer this question, researchers asked participants to complete a questionnaire called the **Treatment Satisfaction Questionnaire for Medication (TSQM-9)** at the start of the trial, Month 6, and Month 12. This questionnaire asked about how well **ofatumumab** worked, including any adverse events, and how easy it was to use.



Researchers found that in general, participants were satisfied with the treatment, including how well it worked, the ease of use, and the overall experience.

What medical problems, also called adverse events, happened during this trial?

Trial doctors keep track of all medical problems, also called **adverse events**, that happen in trials. They track adverse events 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 year and 6 months after the last dose of **ofatumumab**.

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.



- 86 out of 102 had adverse events.
- 6 participants had adverse events that were considered serious.
- 5 participants left the trial due to an adverse event.
- None of the participants died.

The researchers concluded there were no new safety concerns for **ofatumumab** in this trial.

How many participants had adverse events?

Ofatumumab 102 participants		
Had at least 1 adverse event, including serious and other	86 of 102 84%	<div><div></div></div>
Had at least 1 serious adverse event	6 of 102 6%	<div><div></div></div>
Left the trial due to an adverse event	5 of 102 5%	<div><div></div></div>

What serious adverse events did the participants have?

6 participants had serious adverse events.

The list below shows all the serious adverse events that happened. Some participants had more than one serious adverse event.

- **COVID-19**
- **Muscle inflammation caused by an infection** (Infective myositis)
- **Severe complication of a urinary infection** (Urosepsis)
- **Injury to the nerve in the lower back** (Sciatic nerve injury)
- **Issue with a blood vessel repair** (Vascular graft complication)
- **Pain in the arms or legs** (Pain in extremity)
- **Stroke** (Cerebrovascular accident)
- **Blood clot in a deep vein, usually in the leg** (Deep vein thrombosis)

What other adverse events (not including serious) did the participants have?

The table below shows the most common adverse events.

Ofatumumab 102 participants		
COVID-19	31 of 102 30%	<div><div></div></div>
Headache	12 of 102 12%	<div><div></div></div>
Tiredness Fatigue	12 of 102 12%	<div><div></div></div>
Urinary infection Urinary tract infection	11 of 102 11%	<div><div></div></div>
Fever Pyrexia	6 of 102 6%	<div><div></div></div>
Itching Pruritus	6 of 102 6%	<div><div></div></div>

What was learned from this trial?

Researchers learned more about the effects of **ofatumumab** in people with **relapsing multiple sclerosis** who previously received similar treatment.



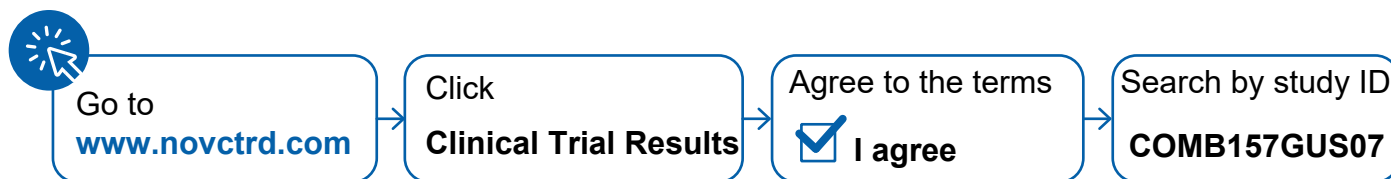
- The researchers concluded that overall, participants had the same or fewer active brain lesions after 1 year of treatment with **ofatumumab**.
- Researchers also concluded that most participants remained on **ofatumumab** treatment through 6 and 12 months and were satisfied with the treatment.
- Researchers did not find any new safety concerns with the use of **ofatumumab** in this trial.

When this summary was written, other studies 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 **NCT04486716**

Other trials of **ofatumumab** may appear on the public websites above. When there, search for **ofatumumab** or **OMB157**.

Full clinical trial title: A single-arm, prospective, multi-center study to explore maintained efficacy with ofatumumab therapy in patients with relapsing multiple sclerosis who discontinue intravenously delivered anti-CD20 monoclonal antibody (aCD20 mAb) therapy (OLIKOS)



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