

Clinical Trial Results Summary

A clinical trial to learn more about the effects of ofatumumab in people with relapsing multiple sclerosis from China

Thank you!

Thank you to the participants who took part in the clinical trial for **relapsing 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: COMB157G2402

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

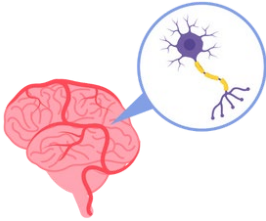
Sponsor: Novartis

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** in people with relapsing multiple sclerosis from China. This trial was done after approval of **ofatumumab** in China to confirm its effects and safety as part of a regulatory commitment.



Multiple sclerosis (MS) is a condition of the brain and spinal cord. In MS, myelin, the layer that protects the nerves, is damaged, leading to the formation of lesions in the brain or spinal cord. This makes it difficult for the brain to communicate with the rest of the body. Symptoms of MS can include weakness, numbness or tingling, trouble seeing, and balance issues.

Relapsing MS is a type of MS in which symptoms – like muscle weakness and walking problems – come back (relapse) or get worse.



Ofatumumab is a medicine approved in China, Europe, and the United States for treating **relapsing MS**. It works by lowering the number of B-cells (a type of white blood cells) and prevents them from causing inflammation and damage to the nerve coating.



Trial drug

OMB 157 also called **ofatumumab**

Pronounced as

oh-fah-TOO-moo-mab



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

- During the trial, how often did participants have MS relapses in a year?
- 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 July 2022 and ended in February 2025. The participants were in the trial for up to 1 year and 6 months.

When the trial ended, the researchers collected information from participants and created a report of the trial results. This summary is based on that report.

Who was in this trial?



99 participants with **relapsing MS** received treatment in this trial—63 women and 36 men. Participants' ages ranged from 18 to 55 years. Their average age was 33 years. All the participants were from China.

Participants could take part in this trial if they:

- were Chinese and between 18 and 55 years of age.
- were diagnosed with **relapsing MS** with at least 1 relapse in a year or 2 relapses in 2 years before joining the study.
- had mild to moderate disability and could walk without help.

What treatment did the participants receive?

The treatment in this trial was:



Ofatumumab: Participants received 20 milligrams (mg) of **ofatumumab** as an injection under the skin at Weeks 0, 1, and 2, followed by one injection each month for about 1 year.

The participants, researchers, and trial staff knew what treatment the participants were receiving.

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



99 participants received **ofatumumab** injection under the skin.

Participants received 3 injections of **ofatumumab** at Weeks 0, 1, and 2, followed by one injection each month for about 1 year. The first injection was given at the clinical site, and later injections could be taken at home.

Participants came back to the clinic at Week 4 and then every 3 months for a health check-up.

After treatment

Up to 6 months



Trial staff checked participants' general health and for any medical problems for up to 6 months after participants' last dose of trial treatment, except for those who continued with **ofatumumab** outside of this trial.

What were the main results of this trial?

During the trial, how often did participants have MS relapses in a year?



Researchers found that participants had around 0.05 MS relapses in a year during treatment with **ofatumumab**.

To answer this question, researchers counted every relapse, including **confirmed relapses**, that happened during the treatment for each participant and calculated the **annualized relapse rate (ARR)**.

In this study, the **annualized relapse rate (ARR)** was the average number of **confirmed relapses** a person would have in a year.

A **confirmed relapse** is an MS flare-up that a doctor checks and confirms using a tool called the **Expanded Disability Status Scale (EDSS)**. The **EDSS** helps doctors understand how MS affects the nervous system, including everyday abilities such as walking, balance, coordination, vision, and bladder control. It helps track how symptoms change over time.



Overall, the ARR across the 99 participants for confirmed relapses was 0.05.

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 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.



Researchers found that:

- 69 out of 99 (70%) participants had adverse events.
- No participants had adverse events that were considered serious.
- None of the participants died.
- None of the participants left the trial due to an adverse event.


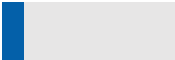
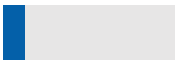


The researchers concluded there were no new safety concerns for **ofatumumab** in this trial.

What serious adverse events did the participants have?

None of the participants had serious adverse events.

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


The table below shows the most common other adverse events.

	Ofatumumab (99 participants)	
Problems caused by an injection Injection-related reaction	43 of 99 43%	
COVID-19	12 of 99 12%	
Infection of the nose and throat Upper respiratory tract infection	12 of 99 12%	
Infection in the urinary system Urinary tract infection	7 of 99 7%	
Fever Pyrexia	7 of 99 7%	

What was learned from this trial?

Researchers learned more about the effects of **ofatumumab** in people with **relapsing multiple sclerosis (MS)** from China.

The researchers concluded that:

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- that participants had around 0.05 MS relapses in a year during treatment with **ofatumumab**.
 - the effects of **ofatumumab** seen in this trial were consistent with those seen in previous trials.
 - there were no new safety concerns with the use of **ofatumumab** in this trial.

When this summary was written, studies with **ofatumumab** were ongoing in relapsing multiple sclerosis.

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 the following websites:

- clinicaltrials.gov – search using the number **NCT05199571**

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

Full clinical trial title: A 12-month, open-label, prospective, multicenter, interventional, single-arm study assessing the efficacy and safety of ofatumumab 20 mg s.c. injection in relapsing multiple sclerosis (RMS) patients in China



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