NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn about the effects of fingolimod in Chinese adolescents and adults with relapsing multiple sclerosis

Thank you!

Thank you to the participants who took part in the clinical trial for **relapsing multiple sclerosis (RMS)**. Every participant helped the researchers learn more about the trial drug **fingolimod**.

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: CFTY720D2419

Novartis drug studied: **Fingolimod,** also called **FTY720.**

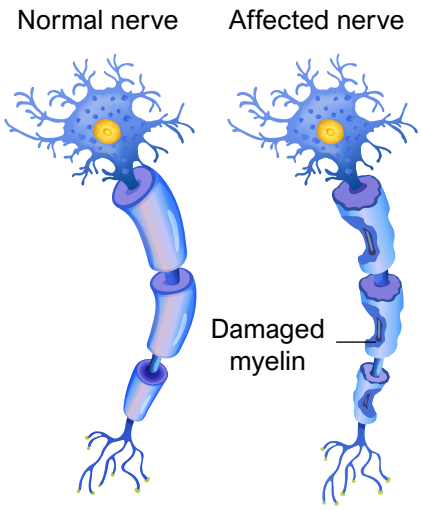
Sponsor: Novartis

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 main purpose of this trial was to learn about the effects of **fingolimod** in Chinese adolescents and adults with **relapsing multiple sclerosis (RMS)**.



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, causing various symptoms.

Common symptoms of **MS** are:

- Muscle weakness
- Numbness or tingling
- Vision problems
- Tiredness
- Walking difficulties
- Problems with coordination and balance

People with **relapsing MS** have new symptoms after a period of improvement or worsening of existing symptoms. **MS** can begin at any age. While it is more common in adults, it can also affect children and teenagers.

Drug
fingolimod

Pronounced as
fin-GOH-li-mod

The trial drug, **fingolimod**, is already approved in China for adolescents and adults with **RMS**. It is thought to work by stopping too many immune cells from reaching the brain and spinal cord. By doing this, **fingolimod** helps reduce the number of MS relapses and slows down damage to the nerves.

This trial was done to learn more about effects of **fingolimod** in Chinese adolescents and adults with **RMS** as part of a commitment to the health authority in China.

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

- How many **MS** relapses did participants have 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 February 2021 and ended in March 2025. Participants could be in this trial for up to 27 months. They could leave the trial at any time after discussing with their doctor.

When the trial ended, researchers created a report of the trial results. This summary is based on that report.

Who was in this trial?

98 participants from **China** with **RMS** received treatment in this trial.

Participants' ages ranged from 10 to 61 years. Their average age was 13 years for adolescents and 32 years for adults.

The number of participants by sex are shown below.

Sex (Adolescents)

8 Male	3 Female

Sex (Adults)

51 Female	36 Male

Participants **could take part** in this trial if they:

- Were between 10 and 65 years of age
- Had **RMS** with at least 2 relapses in the past 2 years or 1 relapse in the past year
- Did not have heart problems or other serious medical conditions

What treatments did the participants receive?

Researchers studied the following treatment.

Fingolimod: 0.5 milligrams (mg), provided as capsules, taken by mouth, once a day.

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

What happened during this trial?

Before treatment

Up to 1 month

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

During treatment

Up to 24 months

A total of 98 participants received treatment with **fingolimod** during this trial.

They were divided into 2 groups based on their age.

Adolescents (10 to 17 years)	Adults (18 years and older)
11 participants	87 participants

All participants received their first dose in the study clinic on Day 1, and were monitored for 6 hours after the dose. They took the remaining doses at home.

After the first dose, participants visited the clinic for check-ups at Month 1, Month 3, and then every 3 months until the end of treatment.

After treatment

Up to 2 months

Participants had a safety follow-up visit 2 months after the last dose.

Trial staff checked the participants' general health throughout the trial.

What were the main results of this trial?

How many MS relapses did participants have in a year?

The results showed that a participant taking **fingolimod** daily could expect to have fewer than 1 relapse per year.

Researchers wanted to find out the number of **MS** relapses participants had over the course of a year. Trial doctors regularly checked participants for **MS** symptoms.

A relapse is when **MS** symptoms get worse or new symptoms appear. The symptoms must last at least 24 hours and cannot be caused by a fever or infection.

To confirm a relapse, trial doctors looked for clear changes in how the nervous system was working. They used a tool called the **Expanded Disability Status Scale (EDSS)** to measure these changes.

The **EDSS** helps doctors understand how **MS** affects everyday abilities such as walking, balance, coordination, vision, and bladder control. This scale helps to track how symptoms change over time. When possible, relapses were confirmed within 7 days after symptoms began.

Researchers looked at the information in a few ways to find out how many relapses participants had in a year.

Main results (adults)

For the main result, researchers looked only at adults, as only a small number of adolescent participants were part of the trial.

Researchers counted how many relapses each participant had during the trial and how long they were in the trial. They used this information to calculate the average number of relapses a participant would have in one year.

They found that:

- Adult participants had about **0.02 relapses per year**.

Other results (adults and adolescents)

Researchers also used 2 other methods to answer the main question:

1. By participant: Researchers counted the total number of relapses each participant had during the trial, and divided that by how long they were in the trial.

2. By time: Researchers counted the total number of relapses that **all** participants had during the trial, and divided that by the total time **all** participants spent in the trial.

For each method, researchers calculated the results separately for adolescents and adults.

They found that:

- Adults had between **0.02 and 0.04 relapses per year**.
- Adolescents had about **0.05 relapses per year**.

Overall, most participants had far less than 1 relapse per year while taking **fingolimod**.

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 the treatment up to 2 months after the 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.

A total of **97 out of 98 participants** had adverse events.

- **15 out of 98 participants** had adverse events that were considered serious.
- **2 out of 98 participants** left the trial due to an adverse event.
- None of the participants died during the trial.

There were no new or unexpected safety concerns with **fingolimod**.

How many participants had adverse events?

The table below shows how many participants had adverse events during the treatment.

Participants who:	Adolescents (11 participants)	Adults (87 participants)
Had at least 1 **Adverse event (including serious and other)**	11 of 11 **(100%)**	86 of 87 **(99%)**
Had at least 1 **Serious adverse event**	3 of 11 **(27%)**	12 of 87 **(14%)**
Left the trial **due to an adverse event**	0 of 11 **(0%)**	2 of 87 **(2%)**

What serious adverse events did the participants have?

The table below shows the most common serious adverse events that happened during the trial.

	Adolescents (11 participants)	Adults (87 participants)
Liver injury	0 of 11 **(0%)**	3 of 87 **(3%)**
Liver injury caused by drug Drug-induced liver injury	0 of 11 **(0%)**	2 of 87 **(2%)**
COVID-19	0 of 11 **(0%)**	2 of 87 **(2%)**
Sudden, uncontrolled brain activity Seizure	2 of 11 **(18%)**	0 of 87 **(0%)**

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

The table below shows the most common other adverse events that happened during the trial.

	Adolescents (11 participants)	Adults (87 participants)
Lymphocyte count decreased (a type of white blood cell)	2 of 11 **(18%)**	53 of 87 **(61%)**
COVID-19	2 of 11 **(18%)**	35 of 87 **(40%)**
Increased liver protein Alanine aminotransferase increased	2 of 11 **(18%)**	33 of 87 **(38%)**
Low levels of lymphocytes Lymphopenia	7 of 11 **(64%)**	24 of 87 **(28%)**
Low levels of white blood cells Leukopenia	5 of 11 **(45%)**	22 of 87 **(25%)**
White blood cell count decreased	4 of 11 **(36%)**	22 of 87 **(25%)**
Nose and throat infection Upper respiratory tract infection	4 of 11 **(36%)**	21 of 87 **(24%)**

What was learned from this trial?

This trial helped researchers learn about the effects of **fingolimod** in participants with **relapsing multiple sclerosis (RMS).**

The researchers concluded that:

- Majority of the participants did not have **MS** relapses after treatment.
- There were no new or unexpected safety concerns with **fingolimod**. The safety results were similar to those seen in previous trials.
- The effects of **fingolimod** seen in this trial were similar to those previously seen in China.

When this summary was written, the sponsor had no plans for future trials of **fingolimod** in people with **RMS**.

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:

Go to www.novctrd.com → Click **Clinical Trial Results** → Accept the terms ☑ **I accept** → Search for **CFTY720D2419**

For more information about this trial go to this website:

clinicaltrials.gov – search using the number **NCT04667949**

Other trials with **fingolimod** appear on the public websites above. When there, search for **fingolimod** or **FTY720**.

Full clinical trial title: A 24-month, open-label, prospective, multicenter interventional, single-arm study assessing the efficacy and safety of fingolimod (Gilenya) 0.5 mg in relapsing multiple sclerosis (RMS) patients in China

NOVARTIS

Novartis is a global healthcare company based in Switzerland that provides solutions to address the evolving needs of patients worldwide.

1-888-669-6682 (US); +41-61-324 1111 (EU)

www.novartis.com/clinicaltrials