Clinical Study Results

Inspired by patients. Driven by science.

Study Sponsor: UCB Biopharma SRL

Drug Studied: Rozanolixizumab

Protocol Number: MG0020

Short Study Title: A study to compare 2 different ways for people living with generalized myasthenia gravis to give themselves injections of rozanolixizumab

Thank you

UCB thanks all the participants of this study. All the participants helped the researchers learn more about using rozanolixizumab in people living with generalized myasthenia gravis.

This is a summary of the main results of this study. An independent, non-profit organization helped prepare this summary of the study results, which included feedback from patients.

We think it is important to share the results with the participants and the public. We hope this summary helps the participants understand their important role in medical research.

The purpose of this summary is only to share information. If you need medical advice, please contact your doctor. If you participated in this study and have questions about the results, please speak with study staff.

This summary was approved by UCB Biopharma SRL on 24 April 2025. The information in this summary is current as of this date.

Overview of this study

Why was the research needed?

Researchers are looking for ways that people living with generalized myasthenia gravis can give themselves the drug rozanolixizumab.

What treatment did the participants take?

The participants in this study gave themselves injections of rozanolixizumab using 2 different methods: the **manual push method** and a **syringe driver**.

What were the results of this study?

The main questions the researchers wanted to answer in this study were:

- **Were the participants able to give themselves rozanolixizumab using each injection method?**

  Yes. All of the participants were able to give themselves rozanolixizumab using both the manual push method and a syringe driver.

The researchers also wanted to know:

- **How many participants had medical problems during this study?**

  There were 75.8% of participants (47 of 62) who had a medical problem in this study.

  In one part of the study, 31.5% of participants (17 of 54) had a medical problem while giving themselves rozanolixizumab using a syringe driver, and 34.0% of participants (18 of 53) had a medical problem while giving themselves rozanolixizumab using the manual push method.

- **What medical problems did the study doctors report as possibly related to study treatment?**

  There were 35.5% of participants (22 out of 62) who had medical problems that the study doctors reported as **possibly being related** to study treatment.

  The most common possibly related medical problem was a headache.

- **Did rozanolixizumab improve the participants' generalized myasthenia gravis symptoms?**

  Overall, throughout this study, the researchers found that the participants had improvements in their generalized myasthenia gravis symptoms that were similar to the improvements seen in other rozanolixizumab studies.

More details about the results of this study are included later in this summary.

Where can I learn more about this study?

You can find more information about this study on the websites listed on the last page. If a full report of the study results is available, it can also be found on those websites.

Why was the research needed?

Before a treatment is available to the public, researchers do clinical studies to get information about how well the treatment works and about how safe it is.

The researchers in this study wanted to learn about 2 different ways for participants living with generalized myasthenia gravis to give themselves injections of rozanolixizumab. They also wanted to learn if the participants had any medical problems during the study.

The **immune system** is the body's natural defense system. It fights diseases, infections, and anything it does not recognize as a normal part of the body. But, in people with diseases of the immune system, the immune system attacks the body's own healthy cells. These types of diseases of the immune system are called **autoimmune diseases**.

Generalized myasthenia gravis is a rare autoimmune disease that can lead to extreme muscle weakness throughout the body. This can affect activities or body functions that many people take for granted, including seeing objects clearly, speech, and swallowing. It can also affect the limbs, making it difficult for people to do everyday activities, including working or studying. It is a long-term condition that requires constant and often long-term treatment to improve symptoms.

In people living with generalized myasthenia gravis, proteins in the immune system called **IgG autoantibodies** attack the connections between nerve cells and muscle cells, causing muscle weakness. IgG autoantibodies can also attach to a protein called **FcRn**, which protects them from breaking down and allows them to continue to attack the body for a longer time.

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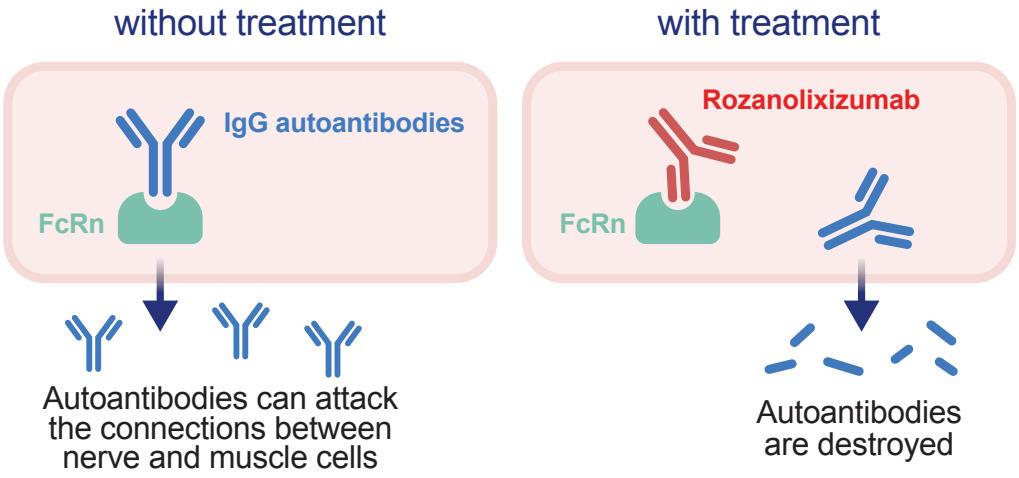
The study drug **rozanolixizumab** is designed to stop antibodies, including IgG autoantibodies, from attaching to FcRn. When these antibodies cannot attach to FcRn, they are broken down by the body more quickly. While lower levels of antibodies in the body may increase the risk of infection, researchers think that lower levels of IgG autoantibodies may help to improve the symptoms of people with generalized myasthenia gravis.

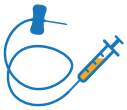
How rozanolixizumab is designed to work



In previous clinical studies, participants received rozanolixizumab from study doctors as an injection just under the skin using a **syringe driver**.

A **syringe driver** is a battery-powered device that continuously gives medicine through a needle just under the skin.

In this study, the researchers wanted to see if the participants could give themselves injections of rozanolixizumab by using syringe drivers or by using a new method called the **manual push method**.



The **manual push method** uses a hand-held syringe connected to a long thin plastic tube that gives medicine through a needle just under the skin.

The manual push method is able to give a dose more quickly than the syringe driver, and it does not require as much equipment. Because of this, researchers think that the manual push method may be easier for some people to use than a syringe driver. For both methods, rozanolixizumab injections are given in the stomach area.

What was the main question studied?

The main question the researchers wanted to answer in this study was:

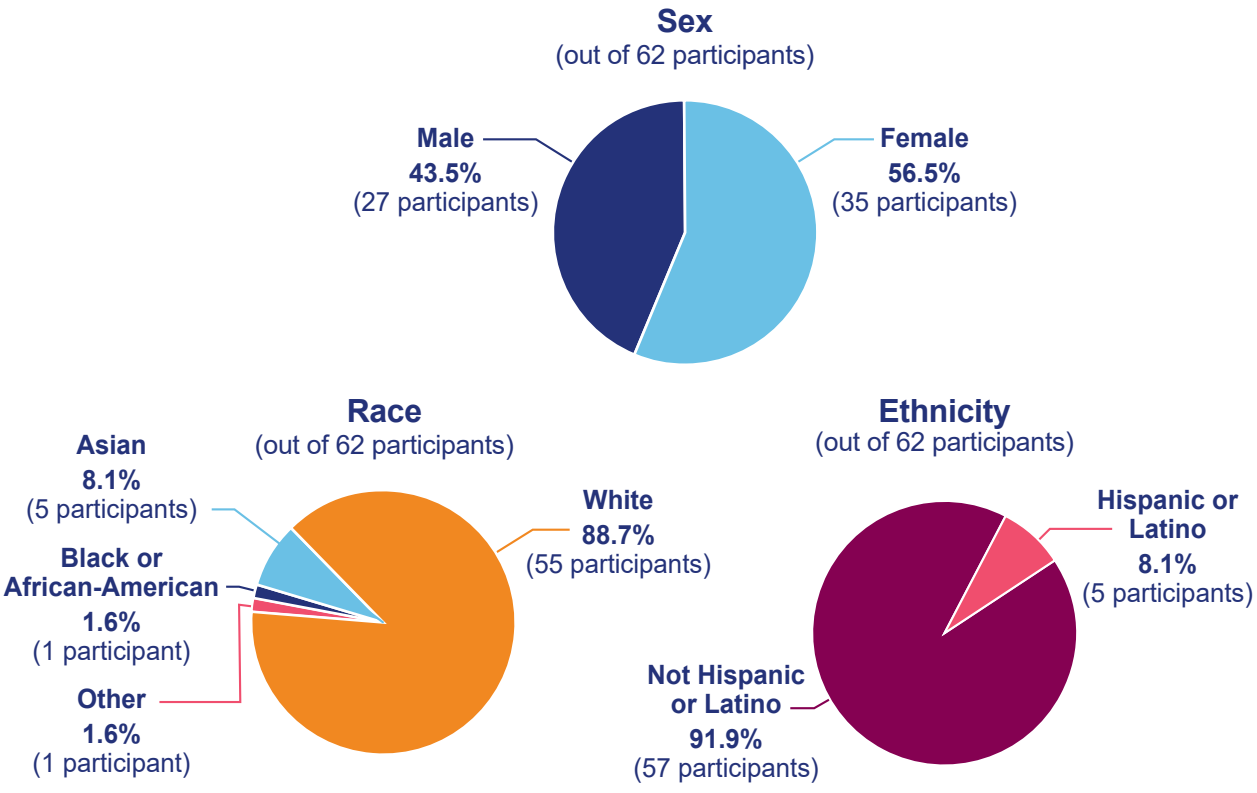
- Were the participants able to give themselves rozanolixizumab using each injection method?

For participants who gave themselves injections of rozanolixizumab, the researchers also wanted to know:

- How many participants had medical problems during this study?
- What medical problems did the study doctors report as possibly related to study treatment?
- Did rozanolixizumab improve the participants' generalized myasthenia gravis symptoms?

Who participated in the study?

There were 62 participants with generalized myasthenia gravis who participated in this study. They were 20 to 80 years old when they joined.



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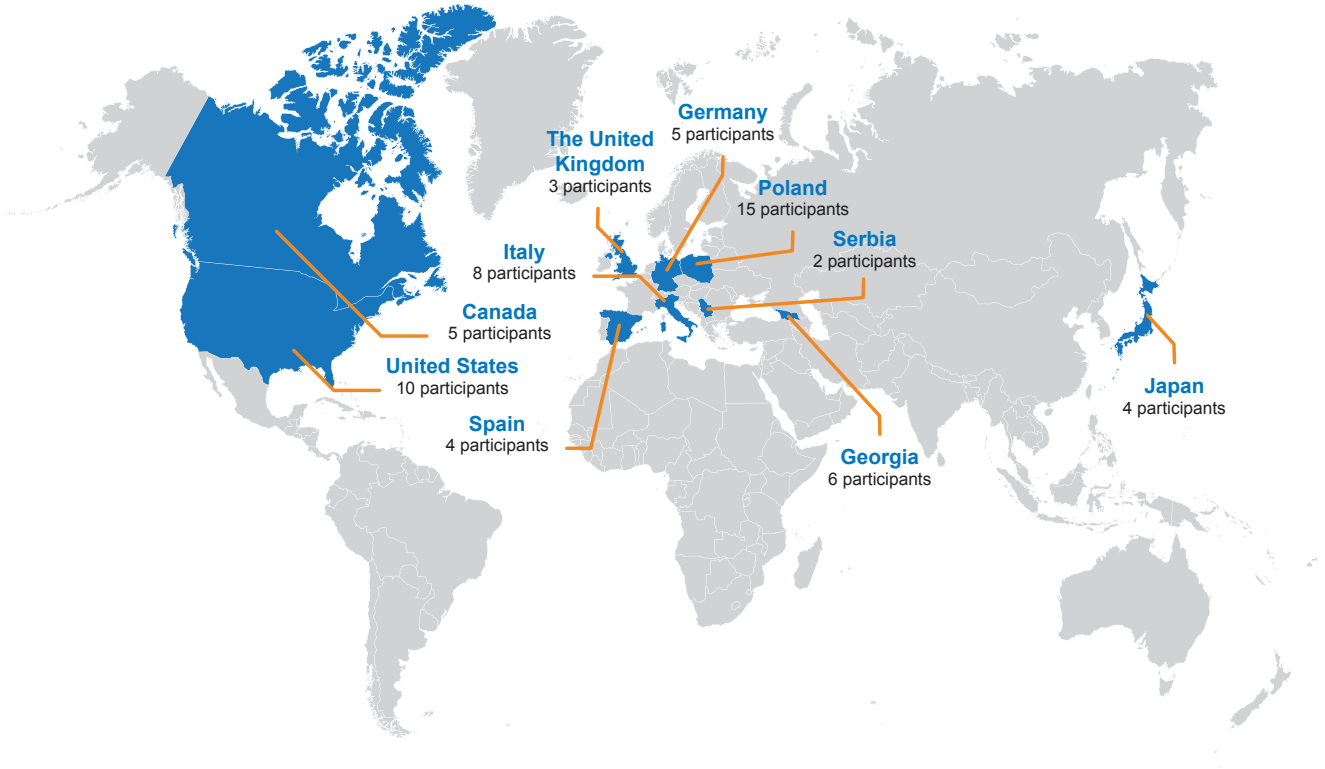
The study included participants in 10 countries.



In this study, the researchers included participants living with generalized myasthenia gravis. The participants were also willing to give themselves injections of rozanolixizumab using both the manual push method and a syringe driver, or had a caregiver who was able to give them the injections.

Each participant who completed the study was in the study for up to 29 weeks. The whole study lasted about 1 year. The study started in April 2023 and ended in April 2024.

What treatment did the participants take?

The participants in this study gave themselves injections of rozanolixizumab using both the manual push method and a syringe driver.

The participants, study doctors, study staff, and UCB staff knew what the participants were taking.

All the participants took rozanolixizumab using both the manual push method and a syringe driver, but in a different order. This helped the researchers see how well each method worked in each participant.

At the beginning of the study, the participants went through a 6-week **training period** when the study staff showed them how to give themselves injections using each method. Then, the participants who successfully completed the training period could start the 2 **self-administration periods**, which lasted 6 weeks each.

At the beginning of the self-administration periods, the researchers used a computer program to randomly choose the order that each participant used the 2 injection methods. This helped make sure the order the participants used for each injection method was chosen fairly and comparing the results for the injection methods was as accurate as possible.

In the self-administration periods, the participants were assigned to 1 of 2 groups. Each group used the 2 injection methods in a different order. The dose of rozanolixizumab each participant took depended on their body weight. Doses were measured in milligrams (mg).

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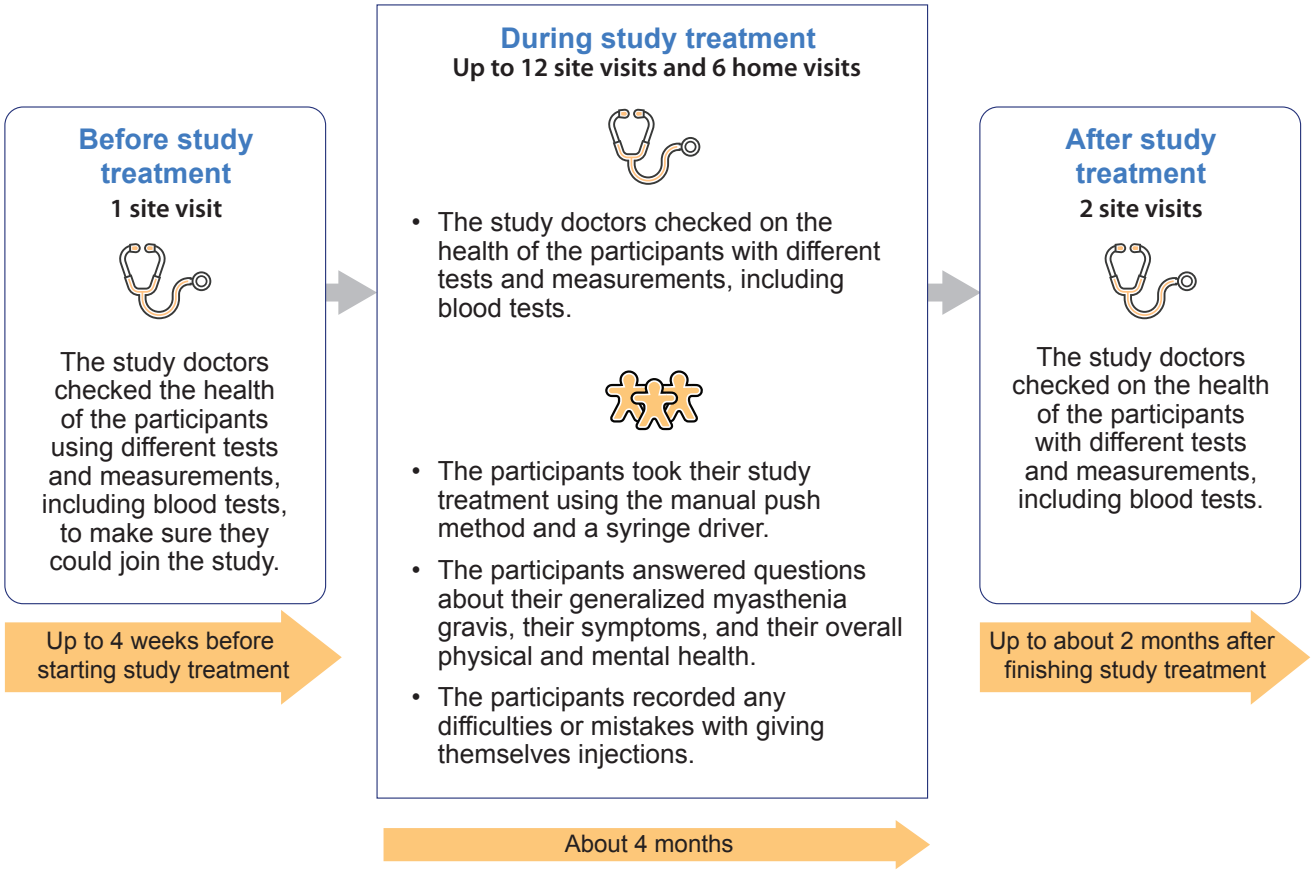
The chart below shows the treatments the researchers planned to study in the self-administration periods. Some of the participants were not able to be assigned to groups in the self-administration period. So, the table below only includes 55 participants.

	Group 1	Group 2
	28 participants	27 participants
	280 mg to 840 mg of rozanolixizumab depending on each participant's weight	
	Self-administration period 1: using a syringe driver **Self-administration period 2:** using the manual push method	**Self-administration period 1:** using the manual push method **Self-administration period 2:** using a syringe driver
	Once a week for 6 weeks during each self-administration period	

What happened during this study?

All the participants first learned about the study and then decided to join. This is called “informed consent”.

The chart below shows what happened in this study for each participant.



What were the results of the study?

This is a summary of the main results from this study. These are the results from all the participants combined. The individual results of each participant might be different and are not in this summary.

Deciding which treatments work best usually takes results from several studies. Other studies may provide new information or different results. Always talk to a doctor before making any treatment decisions.

The results below include 41 out of 55 participants who were assigned to 1 of the 2 groups in the self-administration periods. This is because some participants did not complete the last visit of both self-administration periods. In this section only, the results are shown separately for each injection method.

Were the participants able to give themselves rozanolixizumab using each injection method?

Yes. All of the participants were able to give themselves rozanolixizumab using both the manual push method and a syringe driver.

The researchers kept track of the participants during each self-administration period to see if they were successfully able to give themselves injections using each method. After the last dose in each self-administration period, the researchers checked whether the participants did the following:

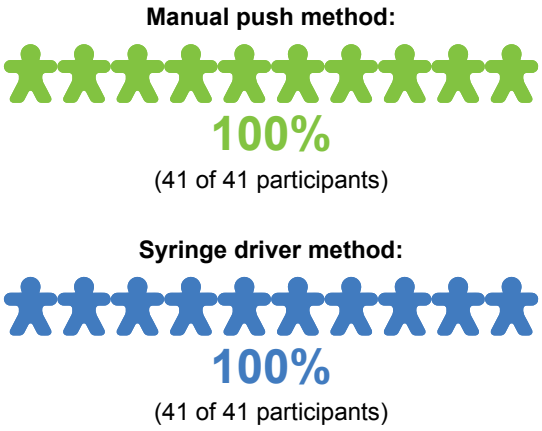
- Gave themselves injections in the correct location
- Gave the injections just under the skin
- Gave themselves the correct dose

In the last dose of each self-administration period, the researchers found that:

- 100% of participants (41 out of 41) successfully gave themselves injections using the manual push method
- 100% of participants (41 out of 41) successfully gave themselves injections using a syringe driver

The graph below shows these results.

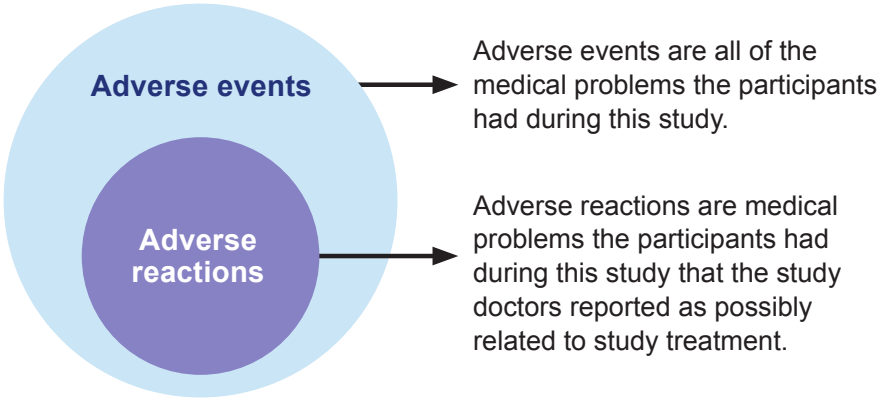
Number of participants who successfully gave themselves injections using each method



How many participants had medical problems during this study?

In this summary, there is information about 2 different types of medical problems that the participants had during the study. An **adverse event** is **any** medical problem that a participant has during a study. Doctors keep track of all adverse events that happen in studies, whether or not these may be related to the study treatment. An **adverse reaction** is different from an adverse event because it is reported by the doctor as **possibly related** to the study treatment. An adverse event or adverse reaction is considered "serious" when it is life-threatening, causes lasting problems, or requires hospital care.

Adverse reactions are adverse events that the study doctors reported as possibly related to study treatment



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The information below is a summary of the **adverse events** that happened in this study.

There were 75.8% of participants (47 out of 62) who had an adverse event in this study.

The table below shows the results for all participants in the **entire study**, and for the participants who used a syringe driver and the manual push method during the **self-administration periods**. Because of this, some of the results include fewer participants.

Adverse events in this study			
	Entire study	**Self-administration periods only**	
	Rozanolixizumab using any method (out of 62 participants)	**Rozanolixizumab using syringe driver** (out of 54 participants)	**Rozanolixizumab using manual push** (out of 53 participants)
How many participants had **serious** adverse events?	11.3% (7 participants) 	5.6% (3 participants) 	1.9% (1 participant) 
How many participants had adverse events?	75.8% (47 participants) 	31.5% (17 participants) 	34.0% (18 participants) 
How many participants left the study due to adverse events?	6.5% (4 participants) 	1.9% (1 participant) 	none 

What medical problems did the study doctors report as possibly related to study treatment?

This section is a summary of the medical problems that the participants had during the study that the doctors reported as **possibly related** to study treatment. These are called "**adverse reactions**".

Some participants had more than 1 adverse reaction.

This summary also includes information about serious adverse reactions. An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems, or requires hospital care.

Other studies may or may not show that these medical problems were possibly related to study treatment. The results from several studies are often needed to decide if a treatment causes an adverse reaction. Always talk to a doctor before making any treatment decisions.

Did any adverse reactions happen during this study?

There were 35.5% of participants (22 out of 62) who had an adverse reaction in this study.

The table below shows the results for all participants in the **entire study**, and for the participants who used a syringe driver and manual push method in the **self-administration periods**. Because of this, some of the results include fewer participants.

Adverse reactions in this study			
	Entire study	**Self-administration periods only**	
	Rozanolixizumab using any method (out of 62 participants)	**Rozanolixizumab using syringe driver** (out of 54 participants)	**Rozanolixizumab using manual push** (out of 53 participants)
How many participants had **serious** adverse reactions?	1.6% (1 participant)	none	none
How many participants had adverse reactions?	35.5% (22 participants)	11.1% (6 participants)	5.7% (3 participants)
How many participants left the study due to adverse reactions?	3.2% (2 participants)	none	none

What serious adverse reactions did the participants have?

In the entire study, 1.6% of participants (1 out of 62) had a serious adverse reaction. This serious adverse reaction was a urinary tract infection.

None of the participants died due to serious adverse reactions.

What adverse reactions did the participants have?

The most common adverse reaction was a headache.

The table below shows the adverse reactions that happened in 2 or more participants in the entire study. There were other adverse reactions, but those happened in only 1 participant each.

Adverse reactions in 2 or more participants in the entire study

Adverse reaction	**Rozanolixizumab using any method** (out of 62 participants)
Headache	16.1% (10)
Fever	4.8% (3)
Diarrhea	4.8% (3)
Nausea	4.8% (3)
Increased levels of creatinine in the blood	3.2% (2)
Decreased levels of IgG in the blood	3.2% (2)
Common cold (Nasopharyngitis)	3.2% (2)
Vomiting	3.2% (2)

Did rozanolixizumab improve the participants' generalized myasthenia gravis symptoms?

Overall, throughout the study, the researchers found that the participants had improvements in their generalized myasthenia gravis symptoms that were similar to the improvements seen in other rozanolixizumab studies.

To test this, the participants answered a questionnaire about their generalized myasthenia gravis symptoms and their ability to do their normal daily activities. This questionnaire is called **Myasthenia Gravis Activities of Daily Living** (**MG-ADL**).

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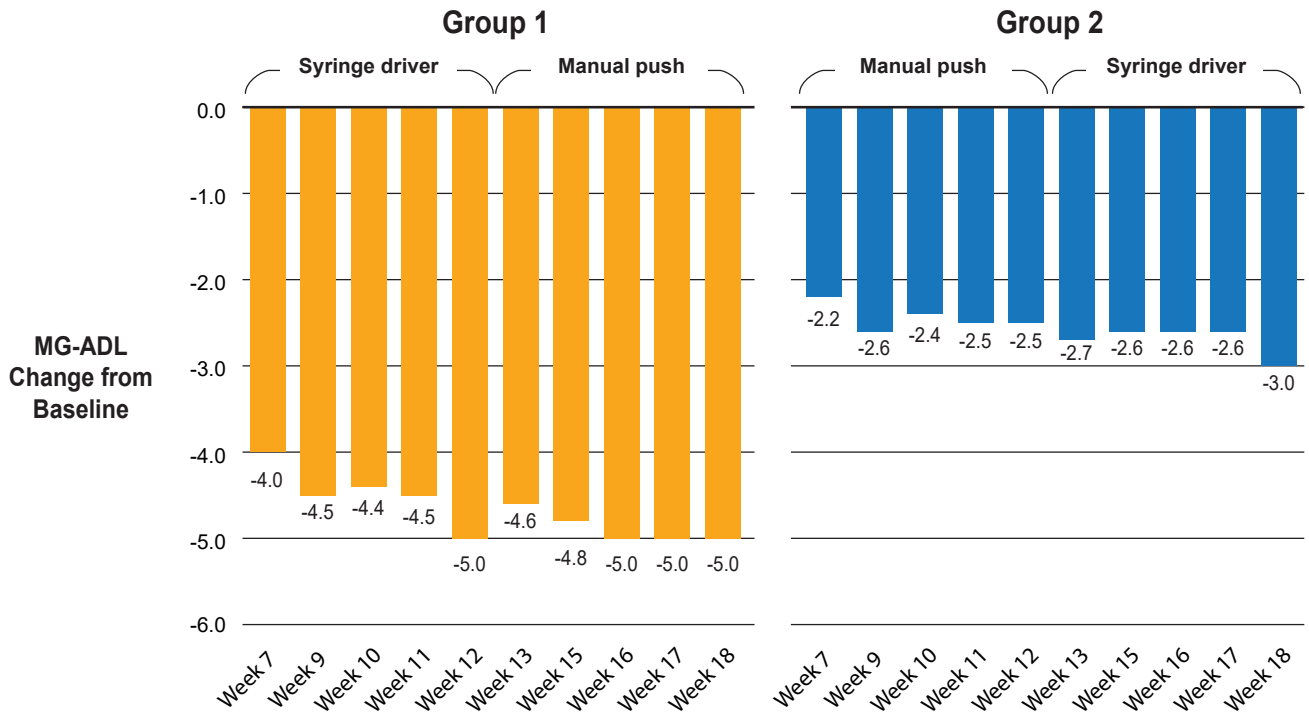
The participants' answers on the questionnaire were given a score. A higher score meant that a person's generalized myasthenia gravis was more severe. The researchers compared each participant's score from before they took study treatment to their score at different times after they had started taking study treatment.

If a participant's scores had **decreased** over time, this meant that their generalized myasthenia gravis symptoms had **improved**. A decrease of 2 points or more in MG-ADL scores means a significant improvement in symptoms.

The graph below shows the amount that each group of participants' overall MG-ADL scores **decreased** each week compared to before starting treatment.

There were also some differences between the participants in Group 1 and the participants in Group 2. These differences were likely due to chance, meaning that they were due to which participants happened to be assigned to which group.

Changes in MG-ADL scores after each week of rozanolixizumab treatment compared to before starting treatment



What did the researchers learn from this study?

The results of this study have helped researchers learn more about using rozanolixizumab in people living with generalized myasthenia gravis. In this study, the researchers found that:

- All participants were able to give themselves injections using both the manual push method and a syringe driver after being trained by the study staff.
- There were 35.5% of participants who had a medical problem that was possibly related to study treatment (adverse reaction). The most common adverse reaction was a headache.
- The participants had improvements in their generalized myasthenia gravis symptoms that were similar to the improvements seen in other studies.

Deciding which treatments work best for patients almost always takes results from several studies. This summary shows only the main results from this one study. Other studies may provide new information or different results.

The purpose of this summary is only to share information. If you need medical advice about your own health or situation, please contact your doctor.

At the time this document was approved, further clinical studies in generalized myasthenia gravis with rozanolixizumab were planned.

Where can I learn more about this study?

You can find more information about this study at the websites listed below:

- www.clinicaltrials.gov/ct2/show/study/NCT05681715
- www.clinicaltrialsregister.eu/ctr-search/search?query=2022-003870-21

If you have questions about this study, UCB contact information is available at www.ucb.com/UCBcares.

Study Information

Protocol Number: MG0020

National Clinical Trial Number: NCT05681715

EudraCT Number: 2022-003870-21

Study Sponsor: UCB Biopharma SRL sponsored this study. It is referred to as UCB in this summary.

Full Study Title: An Open-label, Crossover Study to Evaluate Rozanolixizumab Self-administration by Study Participants With Generalized Myasthenia Gravis

Thank you

Participants in clinical studies belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.

This summary was last updated on 24 April 2025.
The final clinical study report is dated 21 August 2024.