Clinical Study Results

Inspired by patients. Driven by science.

Study Sponsor: UCB Biopharma SRL

Drug Studied: Rozanolixizumab

Protocol Number: FM0001

Short Study Title: A study to learn how well rozanolixizumab works and how safe it is in adults with fibromyalgia

Thank you

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

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 25 July 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 a different way to treat fibromyalgia. Before a drug is available for all patients, researchers do clinical studies to find out how the drug works and how safe it is.

What treatments did the participants receive?

This study had 4 periods. For the first period of this study, all participants received a placebo. For the second and third periods of this study, the participants either received rozanolixizumab or a placebo. For the fourth and final period of this study, all participants received a placebo. A placebo looks like a drug but does not have any medicine in it. More details about the periods of this study are included later in this summary.

What were the results of this study?

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

- **Did rozanolixizumab help improve how much the participants' fibromyalgia pain interfered with their lives compared to the placebo?**

  In this study, there were some differences in the results between the treatment groups after 12 weeks of treatment. But, the researchers could not conclude whether the participants who received rozanolixizumab had a large enough improvement in how much their fibromyalgia pain interfered with their life compared to the participants who received the placebo.

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

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

The following information is about how many participants had medical problems that the study doctors reported as being **possibly related** to study treatment in each period:

- 9.5% of participants (6 out of 63) in the Run-In Period
- 46.0% of participants (29 out of 63) in Treatment Period 1
- 40.4% of participants (23 out of 57) in Treatment Period 2
- 4.8% of participants (1 out of 63) in the Run-Out and Follow-Up Period

The most common possibly related medical problems were headache and pain where the infusion was given.

Where can I learn more about this study?

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

Why was the research needed?

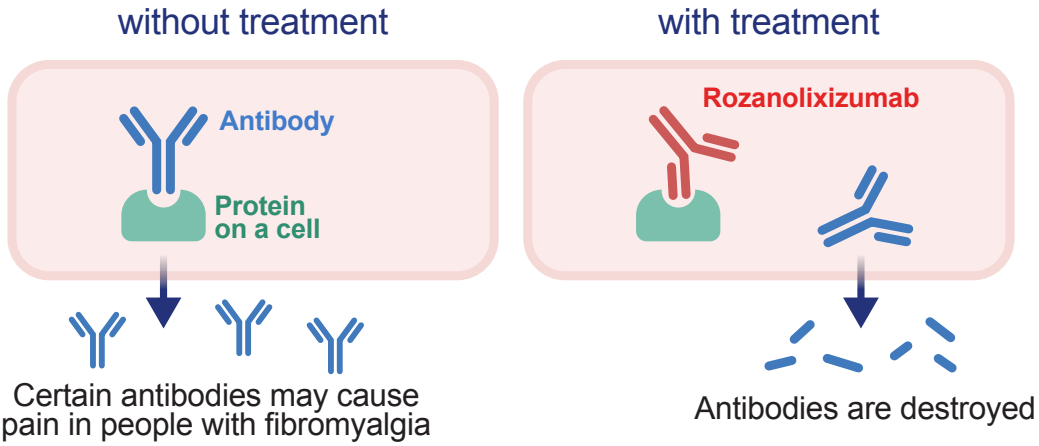
Before a treatment is available to the public, researchers do clinical studies to get information about how well the treatment works and about how safe it is.

The researchers in this study wanted to learn if rozanolixizumab worked in a small number of participants living with fibromyalgia. They also wanted to learn if the participants had any medical problems during the study.

Fibromyalgia is a condition that causes long-lasting pain all over the body. It can also make people very tired and affect their sleep, digestion, thinking abilities, and mood. Current treatments like pain relievers or antidepressants don't work well for everyone, so researchers are looking for new treatment options.

The study drug **rozanolixizumab** is designed to work with the immune system. It decreases the number of certain antibodies that may cause pain and other symptoms in people with fibromyalgia. This study looked at whether rozanolixizumab could safely help reduce pain and improve how people feel and function each day.

How rozanolixizumab is designed to work



What was the main question studied?

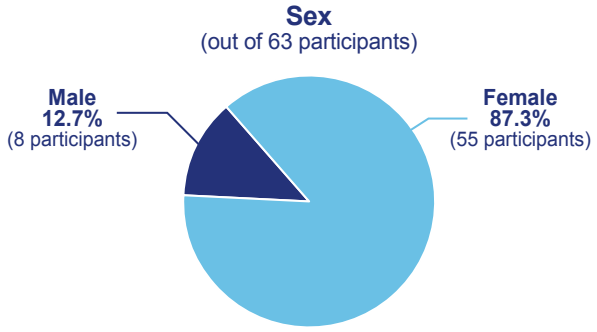
The main question the researchers wanted to answer in this study was:

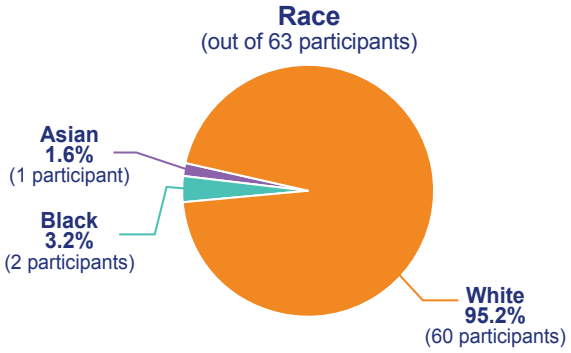
- Did rozanolixizumab help improve how much the participants' fibromyalgia pain interfered with their lives compared to the placebo?

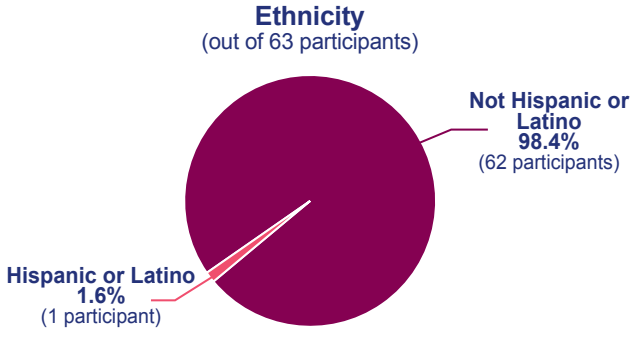
The researchers also wanted to know what medical problems happened that were possibly related to study treatment.

Who participated in the study?

There were 63 participants with fibromyalgia who participated in this study. They were 27 to 67 years old when they joined.







Clinical Study Results

The study included participants in 1 country:

In this study, the researchers included participants living with fibromyalgia who:

- Had been diagnosed with fibromyalgia at least 6 months before joining the study
- Had fibromyalgia pain that made a large negative impact on their daily life

Each participant who completed the study was in the study for up to a little less than 9 months. The whole study lasted about 19 months. The study started in December 2022 and ended in July 2024.

What treatments did the participants receive?

The participants in this study received either rozanolixizumab and a placebo, or only a placebo. A placebo looks like a drug but does not have any medicine in it. The researchers used the placebo to better understand what effects may have been related to rozanolixizumab. Doses of rozanolixizumab were measured in milligrams, also called “mg”.

In this summary, “study treatment” means anything the participants took as a part of the study. This includes rozanolixizumab and the placebo. **Rozanolixizumab** is the drug that the researchers wanted to learn more about.

This study had 4 periods:

- Run-In Period
- Treatment Period 1
- Treatment Period 2
- Run-Out and Safety Follow-Up Period

During the Run-In and Run-Out Periods, the participants did not know what treatment they were receiving. But the study doctors, study staff, and UCB staff did know. Some studies are done this way because if the participants know what treatment they are receiving, this can affect the results of the study.

The Run-In Period was 2 weeks long and **all** participants received the placebo during this time.

During Treatment Periods 1 and 2, none of the participants, study doctors, or study staff knew what treatment each participant was receiving. UCB staff also did not know. Some studies are done this way because knowing what treatment the participants are receiving can affect the results of the study. After the study was completed, UCB learned what treatment each participant received so they could create a report of the results.

During Treatment Periods 1 and 2, the researchers used a computer program to randomly choose if the participants received rozanolixizumab in both periods (Sequence 1), the placebo in both periods (Sequence 3), or the placebo in Treatment Period 1, and rozanolixizumab in Treatment Period 2 (Sequence 2). This helped make sure the treatments were chosen fairly and comparing the results for the treatments was as accurate as possible.

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After Treatment Periods 1 and 2, all participants entered the 2-week Run-Out Period where **all** participants received the placebo. The Safety Follow-Up Period lasted for up to 5 weeks. During the Safety Follow-Up, the study doctors checked on the health of the participants after they finished study treatment.

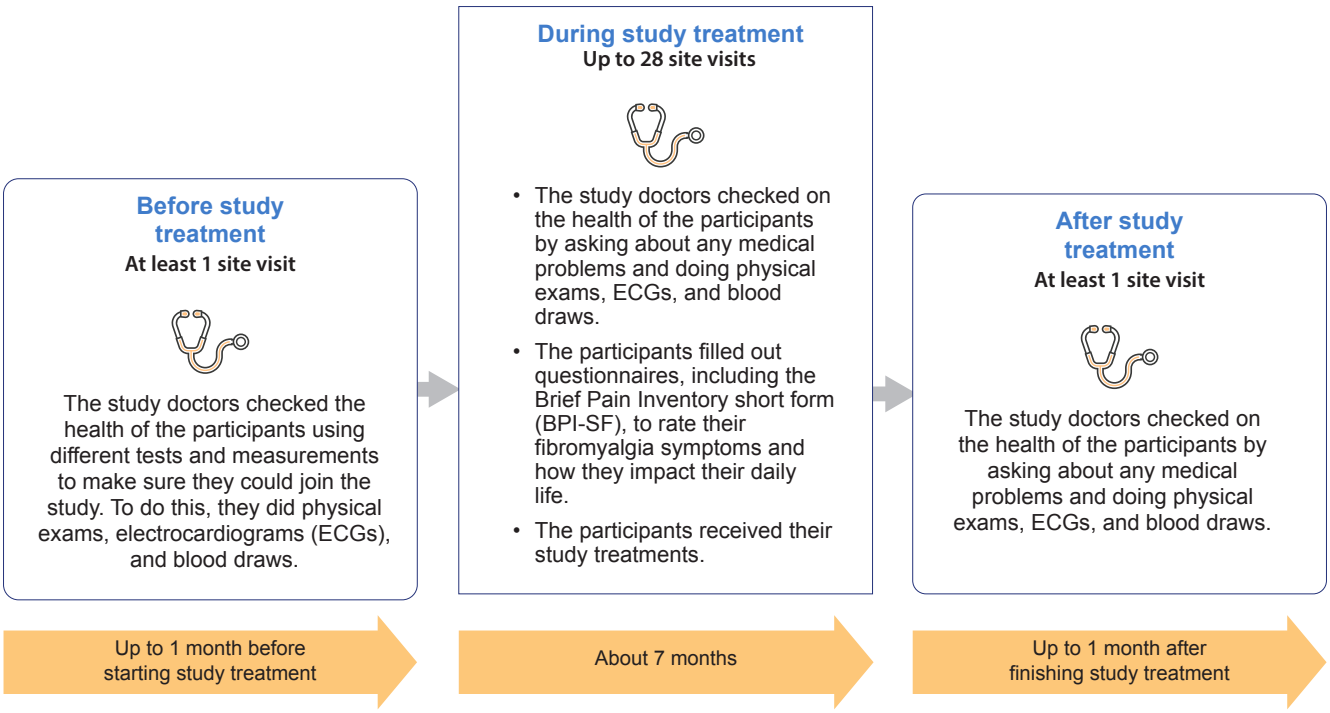
The chart below shows the treatments the researchers planned to study during Treatment Periods 1 and 2:

		Sequence 1	Sequence 2	Sequence 3
		22 participants	20 participants	21 participants
	Treatment Period 1	560 mg of rozanolixizumab once a week for 12 weeks	Placebo once a week for 12 weeks	Placebo once a week for 12 weeks
	Treatment Period 2	560 mg of rozanolixizumab once a week for 12 weeks	560 mg of rozanolixizumab once a week for 12 weeks	Placebo once a week for 12 weeks
		As an infusion just under the skin	As an infusion just under the skin	As an infusion just under the skin

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.

Did rozanolixizumab help improve how much the participants' fibromyalgia pain interfered with their lives compared to the placebo?

In this study, there were some differences in the results between the treatment groups after 12 weeks of treatment. But, the researchers could not conclude whether the participants who received rozanolixizumab had a large enough improvement in how much their fibromyalgia pain interfered with their life compared to the participants who received the placebo.

To answer this question, researchers asked the participants to fill out the Brief Pain Inventory short form (BPI-SF) before and after 12 weeks of treatment with rozanolixizumab or a placebo in Treatment Period 1. On this questionnaire, participants were asked to rate how severe their pain was and how much pain interfered with their daily lives.

The pain interference score was specifically looking at how much pain affects general activity level, mood, ability to walk, work, relationships with other people, sleep, and overall life enjoyment. The pain interference score ranges from 0 to 10. The higher their score, the more the participant's pain interferes with their daily life.

The researchers looked at how the participants' pain interference scores changed from before starting treatment to after 12 weeks of treatment. Then they compared the results between the participants receiving rozanolixizumab and the participants receiving the placebo.

After 12 weeks of treatment, the researchers found that:

- The 22 participants receiving **rozanolixizumab** had an average BPI-SF pain interference score of **5.76**.
- The 41 participants receiving the **placebo** had an average BPI-SF pain interference score of **6.30**.

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 medical problems are called "**adverse reactions**".

During Treatment Periods 1 and 2 in this study, the doctors did not know what the participants were receiving when the medical problems happened. The study doctors reported the medical problems they thought were caused by rozanolixizumab, even though the participants could have received the placebo. So, some adverse reactions may be reported in participants who received the placebo, even though the placebo does not directly cause medical problems.

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.

Some participants **did not** complete Treatment Period 2. So, the results below include fewer participants for Treatment Period 2.

Did any adverse reactions happen during this study?

	Run-In	Treatment Period 1	
	Placebo (out of 63 participants)	**Rozanolixizumab** (out of 22 participants)	**Placebo** (out of 41 participants)
How many participants had **serious** adverse reactions?	none	none	none
How many participants had adverse reactions?	9.5% (6 participants) 	59.1% (13 participants) 	39.0% (16 participants) 
How many participants left the study due to adverse reactions?	none	9.1% (2 participants) 	none

	Treatment Period 2		
	Rozanolixizumab for both treatment periods (out of 18 participants)	**Placebo then rozanolixizumab** (out of 19 participants)	**Placebo for both treatment periods** (out of 20 participants)
How many participants had **serious** adverse reactions?	none	none	none
How many participants had adverse reactions?	38.9% (7 participants) 	52.6% (10 participants) 	30.0% (6 participants) 
How many participants left the study due to adverse reactions?	none	none	none

Run-Out and Follow-Up Period			
	Rozanolixizumab for both treatment periods (out of 22 participants)	**Placebo then rozanolixizumab** (out of 20 participants)	**Placebo for both treatment periods** (out of 21 participants)
How many participants had **serious** adverse reactions?	none	none	none
How many participants had adverse reactions?	none	none	4.8% (1 participant) 
How many participants left the study due to adverse reactions?	none	none	none

What adverse reactions did the participants have?

The most common adverse reactions were headache and pain where the infusion was given.

The tables below shows the adverse reactions that happened in 3 or more participants in any treatment group. There were other adverse reactions, but those happened in fewer participants.

	Run-In	Treatment Period 1	
Adverse reaction	**Placebo** (out of 63 participants)	**Rozanolixizumab** (out of 22 participants)	**Placebo** (out of 41 participants)
Headache	1.6% (1)	27.3% (6)	14.6% (6)
Pain where the infusion was given	4.8% (3)	none	12.2% (5)
A potentially life-threatening overreaction by the immune system in response to treatment (Hypersensitivity)	none	18.2% (4)	none

	Treatment Period 2		
Adverse reaction	**Rozanolixizumab for both treatment periods** (out of 18 participants)	**Placebo then rozanolixizumab** (out of 19 participants)	**Placebo for both treatment periods** (out of 20 participants)
Headache	5.6% (1)	none	5.0% (1)
Pain where the infusion was given	none	10.5% (2)	20.0% (4)
A potentially life-threatening overreaction by the immune system in response to treatment (Hypersensitivity)	5.6% (1)	5.3% (1)	none

Run-Out and Follow-Up Period			
Adverse reaction	**Rozanolixizumab for both treatment periods** (out of 22 participants)	**Placebo then rozanolixizumab** (out of 20 participants)	**Placebo for both treatment periods** (out of 21 participants)
Headache	none	none	none
Pain where the infusion was given	none	none	4.8% (1)
A potentially life-threatening overreaction by the immune system in response to treatment (Hypersensitivity)	none	none	none

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 fibromyalgia. In this study, the researchers found that:

- Rozanolixizumab did not meaningfully help to improve how much the participants' fibromyalgia pain interfered with their lives compared to the placebo.
- Adverse reactions were more common in the participants who were receiving rozanolixizumab compared to the participants who were receiving the placebo.
- The most common adverse reactions over the entire study were headache and pain where the injection was given.

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 fibromyalgia with rozanolixizumab were not planned.

Where can I learn more about this study?

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

- www.clinicaltrials.gov/ct2/show/study/NCT05643794

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

Study Information

Protocol Number: FM0001

National Clinical Trial Number: NCT05643794

EudraCT Number: 2022-001523-32

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

Full Study Title: A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Phase 2a, Proof-Of-Concept Study to Evaluate the Efficacy and Safety of Rozanolixizumab to Treat Adult Study Participants With Severe Fibromyalgia Syndrome

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.

CISCRP REVIEW PANEL

This summary was last updated on 25 July 2025.
The final clinical study report is dated 26 November 2024.