Clinical Study Results

Inspired by patients. Driven by science.

Treatment Studied: Zilucoplan

Protocol Number: DV0012

Study Purpose: A study to learn how zilucoplan moves through the body over time when given in 2 different ways in healthy adults

Thank you

UCB thanks all the participants of this study. All the participants helped the researchers learn more about how zilucoplan acts in the blood of healthy participants.

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 06 November 2025. The information in this summary is current as of this date.

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Overview of this study

Why was the research needed?

Researchers are looking for a different way to give zilucoplan to treat myasthenia gravis. Before a treatment is available for all patients, researchers do clinical studies to find out how the treatment works and how safe it is.

What treatments did the participants receive?

The participants in this study received injections of zilucoplan in a pre-filled syringe and an auto-injector.

What were the results of this study?

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

- **Did zilucoplan move through the body over time similarly when received in a pre-filled syringe and an auto-injector?**

  Yes. Overall, the participants had a similar level of zilucoplan in their blood over time after using a pre-filled syringe and an auto-injector.

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?

There were 35.7% of participants (5 out of 14) who had medical problems that the study doctors reported as **possibly related** to study treatment. The most common possibly related medical problem was a headache.

There were no participants who had medical problems that the study doctors reported as possibly related to the pre-filled syringe or auto-injector.

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.

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Why was the research needed?

Researchers are looking for a different way to give zilucoplan to treat **myasthenia gravis**, which is a type of autoimmune disorder that makes it harder for the nerves and the muscles to communicate. Myasthenia gravis causes weakness and fatigue. It requires constant, often long-term treatment to improve symptoms.

The study drug **zilucoplan** is designed to stop part of the immune system from attacking the body. Zilucoplan is currently approved for treating myasthenia gravis when it is given in a pre-filled syringe. A **pre-filled syringe** is a short tube with a needle that already has the medication in it but needs someone to push the plunger down slowly to give the injection.

Researchers wanted to know if zilucoplan can also be given in an auto-injector. An **auto-injector** is a tube with a needle that already has the medication in it and quickly gives the injection when pressed against the skin.

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

The researchers in this study wanted to learn how zilucoplan moves through the bodies of healthy participants when given in an auto-injector compared to a pre-filled syringe. They also wanted to know if the participants had any medical problems during the study.

A “healthy participant” is someone who does not have the condition the treatment is trying to treat or other serious health conditions. This information is important to know in order to find out if zilucoplan given in an auto-injector can be made available as a treatment option for people living with myasthenia gravis.

pre-filled syringe

A device that already has the medication in it but needs someone to push the plunger

auto-injector

A device that already has the medication in it and quickly gives the injection when pressed against the skin

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What was the main question studied?

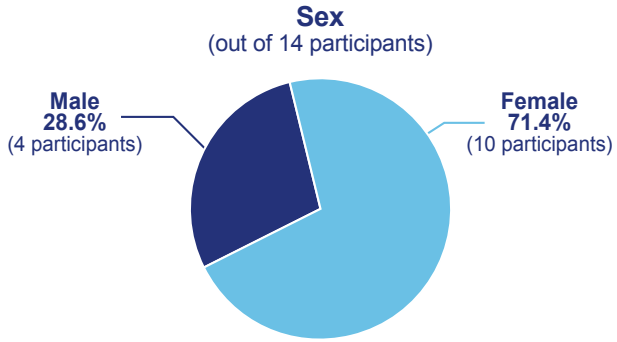
The main question the researchers wanted to answer in this study was:

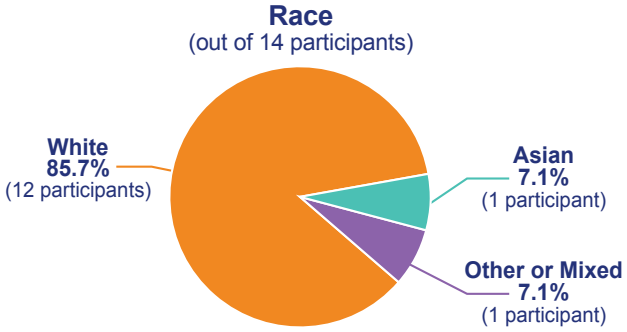
- Did zilucoplan move through the body over time similarly when received in a pre-filled syringe and an auto-injector?

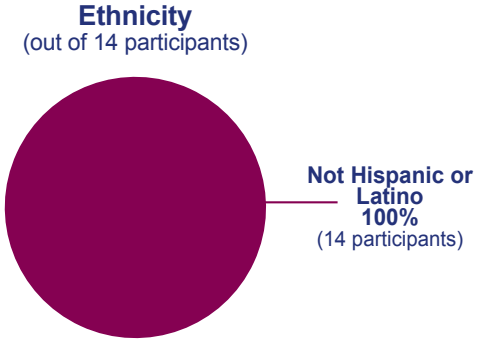
The researchers also wanted to know what medical problems happened that were possibly related to study treatment.

Who participated in the study?

There were 14 healthy participants who participated in this study. They were 21 to 55 years old when they joined. In this study, a “healthy participant” meant a participant who did not have myasthenia gravis or other serious medical problems. Some studies include healthy participants to help researchers know how a treatment moves through the body.







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The study included participants in the Netherlands:

Each participant who completed the study was in the study for about 4 months. The study started in August 2024 and ended in November 2024.

What treatments did the participants take?

The participants in this study received injections of zilucoplan through both a pre-filled syringe and an auto-injector.

There were 2 treatment periods during this study. Half the participants received zilucoplan through a pre-filled syringe during the first treatment period and then through an auto-injector during the second treatment period. The other half of the participants received zilucoplan through an auto-injector during the first treatment period and then through a pre-filled syringe during the second treatment period. This helps researchers see how each participant reacts to both injection types.

There was a washout period between the first treatment period and the second treatment period. During the washout period, the participants did not receive any trial treatment. This was done to make sure the treatment could leave the participants' bodies completely before the next treatment period.

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Clinical Study Results

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

Doses of zilucoplan are measured in milligrams (mg). The dose of zilucoplan that each participant received was based on their body weight.

- Participants who weighed less than 56 kg received 16.6 mg.
- Participants who weighed 56 kg to less than 77 kg received 23.0 mg.
- Participants who weighed 77 kg or more received 32.4 mg.

The chart below shows the treatments the researchers planned to study:

	Group 1	Group 2
Number of participants	7	7
First zilucoplan injection	Pre-filled syringe	Auto-injector
Second zilucoplan injection	Auto-injector	Pre-filled syringe

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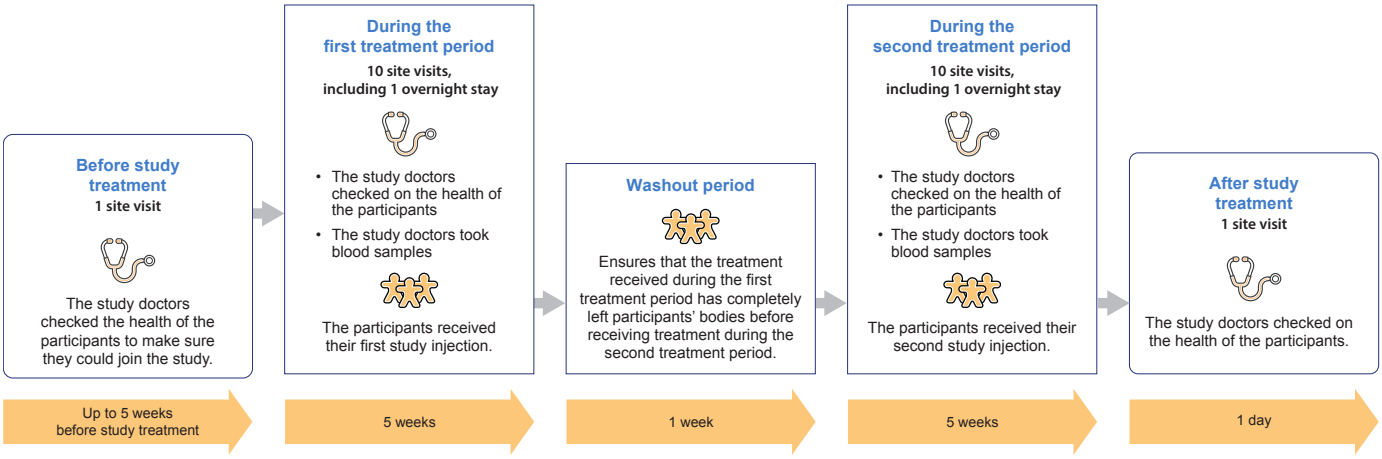
What happened during this study?

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 this 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.

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Did zilucoplan move through the body over time similarly when received through a pre-filled syringe and an auto-injector?

Yes. In this study, the participants had a similar level of zilucoplan in their blood over time after using a pre-filled syringe and an auto-injector.

To answer this question, the doctors took blood samples from the participants before and several times after the participants received zilucoplan in a pre-filled syringe and an auto-injector. Using these blood samples, the doctors measured the amount of zilucoplan to learn:

- The total amount of zilucoplan overall
- The total amount of zilucoplan up until the last blood draw
- The highest amount of zilucoplan

From these blood samples, the researchers found that zilucoplan moved through the body over time similarly when given in a pre-filled syringe and an auto-injector.

The researchers calculated how similar these 3 measurements were after participants received zilucoplan in a pre-filled syringe and an auto-injector. The closer the results were to 100%, the more similar the measurement was for the pre-filled syringe and the auto-injector.

The table below shows the results.

Measurement	Similarity between pre-filled syringe and auto-injector
The total amount of zilucoplan overall	98.09%
The total amount of zilucoplan up until the last blood draw	98.19%
The highest amount of zilucoplan	99.96%

Because the 3 measurements were very close to 100%, the researchers concluded that zilucoplan moved through the body over time similarly when given in a pre-filled syringe and an auto-injector.

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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**".

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 35.7% of participants (5 of 14) who had an adverse reaction in this study.

Adverse reactions in this study

	Zilucoplan in a **pre-filled syringe** (out of 14 participants)	Zilucoplan in an **auto-injector** (out of 14 participants)
How many participants had **serious** adverse reactions?	none	none
How many participants had adverse reactions?	21.4% (3)	14.3% (2)
How many participants left the study due to adverse reactions?	none	none

There were no participants who had medical problems that the study doctors reported as possibly related to the pre-filled syringe or auto-injector.

What serious adverse reactions did the participants have?

There were no participants who had serious adverse reactions during this study.

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What adverse reactions did the participants have?

The most common adverse reaction was headache.

The table below shows all the adverse reactions that happened in this study. Some participants had more than one adverse reaction.

Adverse reaction	Zilucoplan in a **pre-filled syringe** (out of 14 participants)	Zilucoplan in an **auto-injector** (out of 14 participants)
Headache	14.3% (2)	7.1% (1)
Nausea	none	7.1% (1)
Lower abdominal pain	7.1% (1)	none
Dizziness	7.1% (1)	none

What did the researchers learn from this study?

The results of this study have helped researchers learn more about a new way to receive zilucoplan. In this study, the researchers found that:

- Zilucoplan moved through the body over time similarly when given in a pre-filled syringe and an auto-injector.
- 35.7% of participants (5 out of 14) had medical problems that were possibly related to study treatment. The most common possibly related medical problem was a headache.
- No participants had medical problems that were possibly related to the pre-filled syringe or auto-injector.

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.

When this document was approved, further clinical studies with zilucoplan were planned.

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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/NCT06511076
- www.euclinicaltrials.eu/ctis-public/view/2023-508388-64-00

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

Study Information

Protocol Number: DV0012

National Clinical Trial Number: NCT06511076

EU CT Number: 2023-508388-64-00

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

Full Study Title: An open-label, single center, randomized, 2-way crossover, single-dose, bioequivalence study of zilucoplan injected subcutaneously either by prefilled syringe or an auto-injector in healthy adult participants

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 06 November 2025.
The final clinical study report is dated 25 July 2024.

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