Clinical Study Results

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Study Sponsor: UCB Biopharma SRL

Drug Studied: Minzasolmin

Protocol Number: UP0152

Short Study Title: A study to learn how much minzasolmin gets into the body when it is taken as a tablet or capsule, and taken as a tablet with and without food in healthy participants

Thank you

UCB thanks all the participants of this study. All the participants helped the researchers learn more about how minzasolmin 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 22 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 Parkinson's disease. Before a drug is available for all patients, researchers do clinical studies to find out how the drug moves throughout the body and how safe it is.

What treatments did the participants take?

The participants in this study took minzasolmin by mouth in 2 forms: as granules in capsules and as tablets. Participants took the granules in capsules without food, and they took the tablets both with and without food.

What were the results of this study?

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

- **Did the form that minzasolmin was taken in affect how much minzasolmin got into the body?**

  No. Taking different forms of minzasolmin did not have a meaningful effect on how much minzasolmin got into the body.

- **Did eating before taking minzasolmin tablets affect how much minzasolmin got into the body?**

  No. Eating food before taking minzasolmin tablets did not have a meaningful effect on how much minzasolmin got into the body.

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

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

16.7% of participants (3 out of 18) had medical problems that the study doctors reported as **possibly related** to study treatment. The most common possibly related medical problems were headache, and dizziness while sitting, standing, or walking (Dizziness postural).

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 moves throughout the body and about how safe it is.

The researchers in this study wanted to learn how minzasolmin worked in the bodies of healthy participants and if they 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 before additional studies can be done that help find out if minzasolmin can improve the health of people living with Parkinson's disease.

Parkinson's disease, also known as just "Parkinson's", is a condition caused by the damage of specific brain cells in certain parts of the brain. Symptoms of Parkinson's can include uncontrolled movements, disrupted sleep, thinking problems, depression, anxiety, and dementia. Over time, Parkinson's symptoms get worse as more of these brain cells are damaged and die.

In this study, researchers wanted to learn more about the study drug minzasolmin. **Minzasolmin** is designed to slow down the worsening of Parkinson's by decreasing the buildup of a protein called alpha-synuclein. Alpha-synuclein is a normal protein that is found in the body and the brain. When too much of the alpha-synuclein protein builds up in the brain, it can lead to the death of certain brain cells. This is thought to be one of the causes of Parkinson's.

In this study, the researchers wanted to know how much minzasolmin got into the body when taken in different forms. Researchers also wanted to know if eating a high-fat meal before taking minzasolmin affected the way minzasolmin moved in the bodies of healthy participants over time.

What were the main questions studied?

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

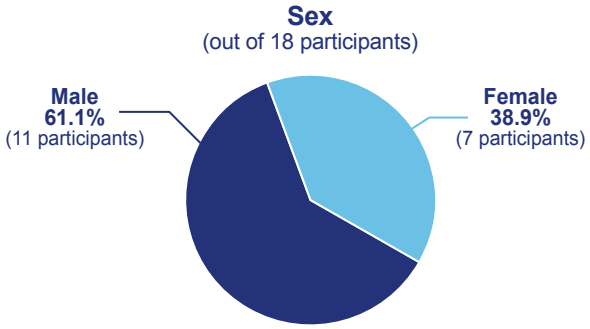
- Did the form that minzasolmin was taken in affect how much minzasolmin got into the body?
- Did eating before taking minzasolmin tablets affect how much minzasolmin got into the body?

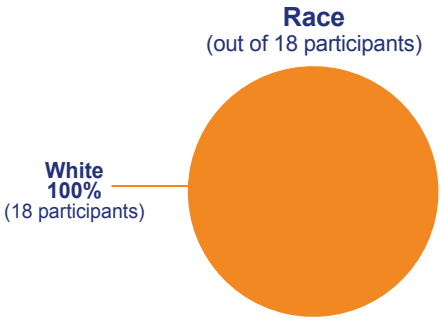
The researchers also wanted to know what medical problems happened that were possibly related to study treatment.

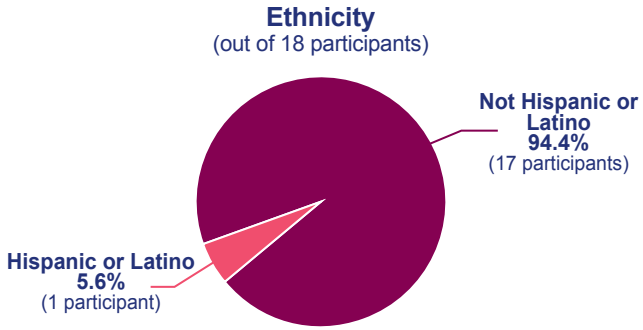
Who participated in the study?

There were 18 healthy participants who participated in this study. They were 32 to 55 years old when they joined.

In this study, a “healthy participant” meant a participant who did not have Parkinson’s or other serious medical problems. Some studies include healthy participants to help researchers know how a treatment moves through the body and if it is safe to use in future studies.







The study included participants in Germany.

Each participant who completed the study was in the study for up to about a month and a half. The whole study lasted 2 and a half months. The study started in September 2024 and ended in November 2024.

What treatments did the participants take?

The participants in this study took minzasolmin. Doses of minzasolmin were measured in milligrams, also called mg.

The original form of minzasolmin is **granules in capsules**. Capsules are pills with an outer shell that hold the medicine. Granules means the medicine inside the capsules looks like little beads.

In this study, the researchers also wanted to learn more about minzasolmin when it is taken as **tablets**. Tablets are solid pills that do not have an outer shell.

In this study, the participants took 180 mg of minzasolmin in 3 different ways:

- As **granules in capsules** after **not eating** since the previous night
- As **tablets** after **not eating** since the previous night
- As **tablets** after **eating** a high-fat meal

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

All the participants took minzasolmin in all 3 ways, but in a different order.

The researchers used a computer program to randomly choose the order that each participant took minzasolmin in the 3 different ways. This helped make sure the order for each participant was chosen fairly and comparing the results was as accurate as possible.

During the study, the participants took minzasolmin a total of **3 times**, with at least **4 days** between each dose. This was done to make sure the minzasolmin could leave their bodies before they took it in the next way. The participants stayed at the study site for about 2 weeks during this part.

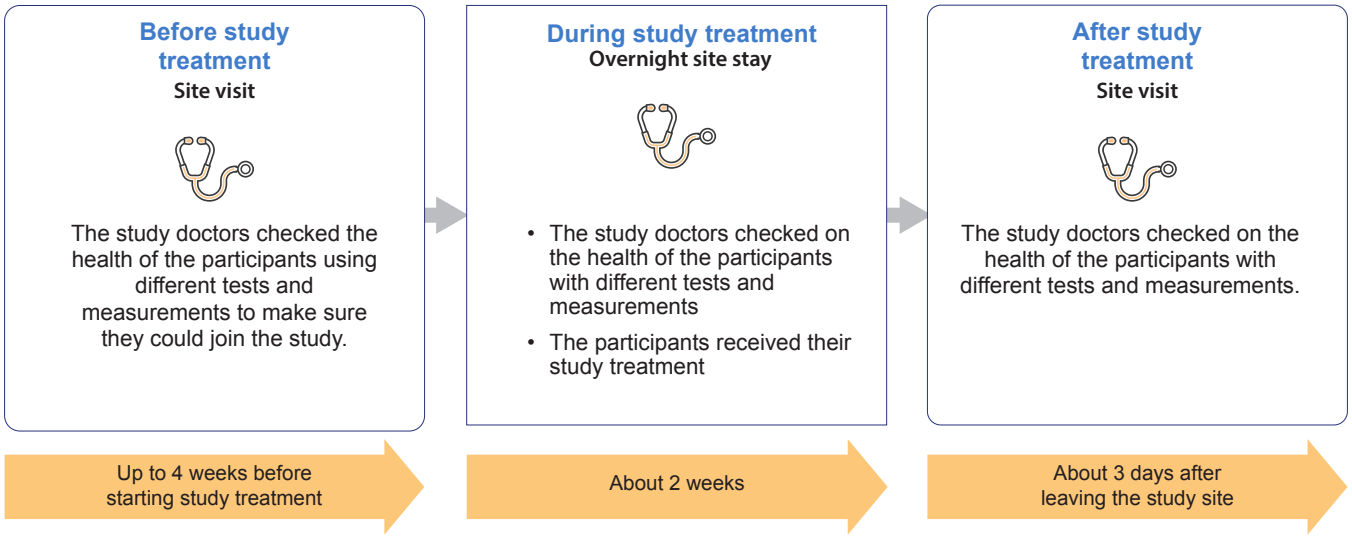
The chart below shows the treatments the researchers studied in all participants:

	Granules in capsules after not eating	Tablets after not eating	Tablets after a high-fat meal
	180 mg of minzasolmin taken as granules in capsules by mouth	180 mg of minzasolmin taken as tablets by mouth	180 mg of minzasolmin taken as tablets by mouth
	1 dose after not eating since the previous night	1 dose after not eating since the previous night	1 dose about 30 minutes after eating a high-fat meal

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 the form that minzasolmin was taken in affect how much minzasolmin got into the body?

No. Taking different forms of minzasolmin did not have a meaningful effect on how much minzasolmin got into the body.

To answer this question, the researchers measured the levels of minzasolmin in the participants' blood after they took minzasolmin as tablets and as granules in capsules after not eating. The researchers saw some differences between the 2 forms of minzasolmin, but they concluded that these differences were not meaningful.

Did eating before taking minzasolmin tablets affect how much minzasolmin got into the body?

No. Eating food before taking minzasolmin tablets did not have a meaningful effect on how much minzasolmin got into the body.

To answer this question, the researchers measured the levels of minzasolmin in the participants' blood after they took minzasolmin as tablets after not eating, and after eating a high-fat meal. The researchers saw some differences between when the participants ate before their dose and when they did not eat before their dose, but they concluded that these differences were not meaningful.

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.

The adverse reactions in this section are shown separately for the 3 ways that the participants took minzasolmin. The results also include the number of participants who had an adverse reaction after **any** of their 3 doses of minzasolmin during this study.

Some participants had more than 1 adverse reaction.

Did any adverse reactions happen during this study?

There were 16.7% of participants (3 out of 18) who had an adverse reaction in this study.

Adverse reactions in this study

	Granules in capsules after not eating (out of 18 participants)	**Tablets after not eating** (out of 18 participants)	**Tablets after a high-fat meal** (out of 18 participants)	**Any of the 3 doses** (out of 18 participants)
How many participants had **serious** adverse reactions?	none	none	none	none
How many participants had adverse reactions?	5.6% (1 participant)	5.6% (1 participant)	16.7% (3 participants)	16.7% (3 participants)
How many participants left the study due to adverse reactions?	none	none	none	none

What serious adverse reactions did the participants have?

None of the participants had a serious adverse reaction.

What adverse reactions did the participants have?

The most common adverse reactions were:

- Headache
- Dizziness while sitting, standing, or walking (Dizziness postural)

Adverse reactions

Adverse reaction	Granules in capsules after not eating (out of 18 participants)	Tablets after not eating (out of 18 participants)	Tablets after a high-fat meal (out of 18 participants)	Any of the 3 doses (out of 18 participants)
Headache	5.6% (1)	none	5.6% (1)	11.1% (2)
Dizziness while sitting, standing, or walking (Dizziness postural)	5.6% (1)	none	5.6% (1)	11.1% (2)
Head discomfort	none	5.6% (1)	5.6% (1)	5.6% (1)
Dry mouth	5.6% (1)	none	none	5.6% (1)
Feeling weak or lacking energy (Asthenia)	none	none	5.6% (1)	5.6% (1)
A sudden feeling of warmth in the upper body (Hot flush)	none	none	5.6% (1)	5.6% (1)

What did the researchers learn from this study?

The results of this study have helped researchers learn more about how much minzasolmin gets into the body when it is taken in different ways, and about its safety.

- Taking different forms of minzasolmin did not have a meaningful effect on how much minzasolmin got into the body.
- Taking minzasolmin after not eating or after eating a high-fat meal did not have a meaningful effect on how much minzasolmin got into the body.
- 16.7% of participants (3 out of 18) had an adverse reaction.
- The most common adverse reactions were headache, and dizziness while sitting, standing, or walking (Dizziness postural).

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 with minzasolmin were not planned.

Where can I learn more about this study?

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

- https://www.clinicaltrials.gov/ct2/show/study/NCT06533475
- https://euclinicaltrials.eu/ctis-public/view/2024-511301-31-00?lang=en

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

Study Information

Protocol Number: UP0152

National Clinical Trial Number: NCT06533475

EU CT Number: 2024-511301-31

Universal Trial Number: U1111-1306-5483

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

Full Study Title: An Open-Label, Randomized Study to Evaluate the Relative Bioavailability of a New Tablet Formulation of Minzasolmin and the Potential Effect of Food on the Pharmacokinetics of Minzasolmin in Healthy 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.

CISCRP REVIEW PANEL

This summary was last updated on 23 July 2025.
The final clinical study report is dated 13 March 2025.