Clinical Study Results

Inspired by patients. Driven by science.

Study Sponsor: UCB Biopharma SRL

Drug Studied: Minzasolmin

Protocol Number: UP0073

Short Study Title: A study to learn how much minzasolmin gets into the body when it is taken in different ways and how safe it is in healthy adults

Thank you

UCB thanks all the participants of this study.

All the participants helped the researchers learn more about how minzasolmin acts in the bodies of healthy participants and about its safety. Minzasolmin is also called UCB0599.

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 17 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 a different way to treat Parkinson's disease. Before a drug is available for all patients, researchers do clinical studies to get information about how well the drug works and about how safe it is.

What treatments did the participants take?

This study had 2 main parts: **Part A** and **Part B**. More information about the participants in each part is included later in this summary.

The participants in **Part A** took different forms of minzasolmin with or without esomeprazole by mouth. The participants in **Part B** took minzasolmin or a placebo by mouth. A placebo looks like a drug but does not have any medicine in it.

What were the results of this study?

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

- **Did the amount of acid in the stomach affect the way minzasolmin moved throughout the body over time when taken in different forms?**
  - **No**. In this study, taking different forms of minzasolmin with or without esomeprazole did not have a meaningful effect on the way minzasolmin moved throughout the body over time. Esomeprazole is a drug that decreases the amount of acid in the stomach.
- **How did minzasolmin move throughout the body over time in Chinese and Japanese participants?**
  - In Part B of this study, minzasolmin moved throughout the body over time in a similar way in Chinese and Japanese participants.
- **What medical problems did Chinese and Japanese participants have during this study?**
  - The most common medical problems in Chinese and Japanese participants were headache and skin redness (Erythema).

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?

There were 40.5% of participants in **Part A** (17 out of 42) who had medical problems that the study doctors reported as **possibly being related** to study treatment. The most common possibly related medical problem in Part A was headache.

There were 22.6% of participants in **Part B** (7 out of 31) who had medical problems that the study doctors reported as **possibly being related** to study treatment. The most common possibly related medical problems in Part B were headache and skin redness (Erythema).

More details about the medical problems in 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 website listed on the last page. When a full report of the study results is available, it also can be found on this website.

Why was the research needed?

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

The researchers in this study wanted to learn how minzasolmin works 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 study drug 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 and how safe it was. Researchers also wanted to know if the amount of acid in the stomach affected the way minzasolmin moved in the bodies of participants over time. To do this, the researchers asked some participants in this study to take a drug called esomeprazole. **Esomeprazole** is a drug that helps decrease acid production in the stomach.

Treatments may work differently for people of different ethnicities or races. In this study, the researchers also wanted to know how minzasolmin affected healthy Chinese and Japanese participants.

The answers to the questions below are important to know before doing more studies in people who have Parkinson's.

What were the main questions studied?

This study had 2 main parts: **Part A** and **Part B**. The researchers had different questions for each part.

The main question the researchers wanted to answer during **Part A** of this study was:

- Did the amount of acid in the stomach affect the way minzasolmin moves throughout the body over time when taken in different forms?

The main questions the researchers wanted to answer during **Part B** of this study were:

- How did minzasolmin move throughout the body over time in Chinese and Japanese participants?
- What medical problems did Chinese and Japanese participants have during this study?

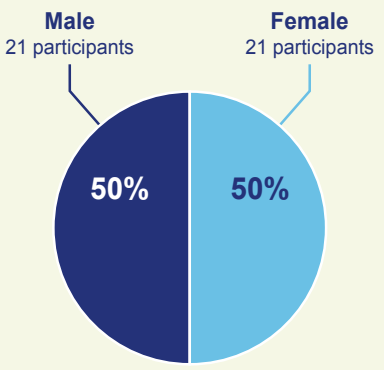
The researchers also wanted to know what medical problems happened that were possibly related to study treatment during the whole study.

Who participated in the study?

In **Part A** of this study, there were 42 healthy participants. They were 20 to 53 years old when they joined.

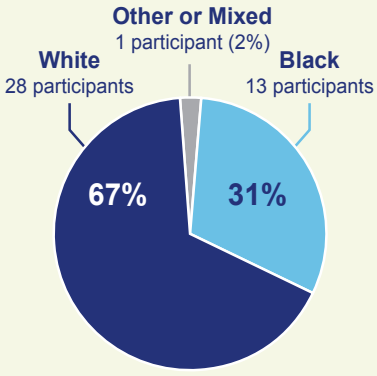
Part A (out of 42 participants)

Sex of participants



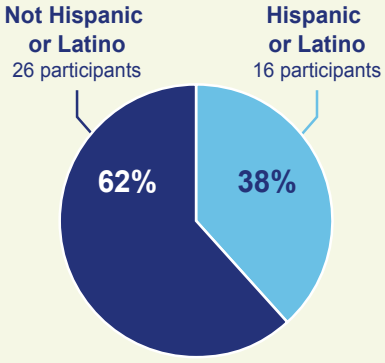
Percentage of participants (%)

Race



Percentage of participants (%)

Ethnicity

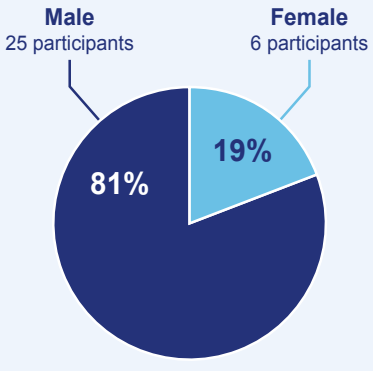


Percentage of participants (%)

Part B included 31 healthy participants: 15 participants were Japanese or of recent Japanese descent and 16 participants were Chinese or of recent Chinese descent. They were 21 to 54 years old when they joined.

Part B (out of 31 participants)

Sex of participants

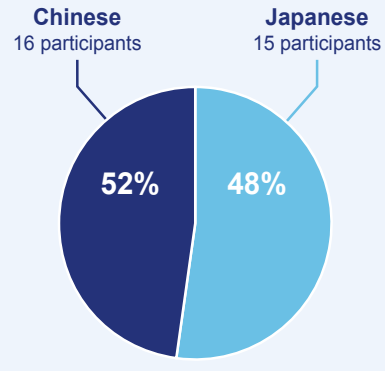


Percentage of participants (%)

Race

Percentage of participants (%)

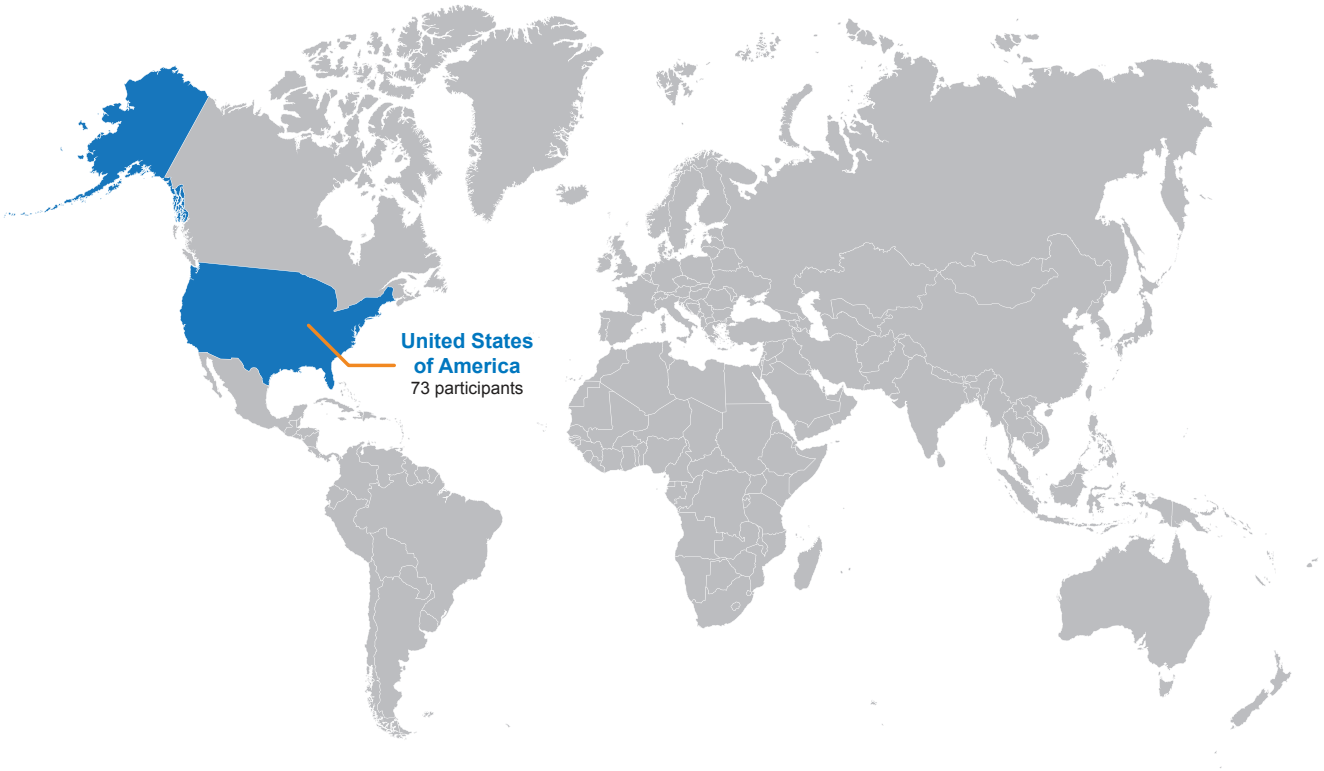
Ethnicity



Percentage of participants (%)

Clinical Study Results

The study included participants in the United States of America.



Each participant who completed **Part A** of the study was in the study for up to **68 days**, and each participant who completed **Part B** of the study was in the study for up to **45 days**. The whole study lasted a little more than 11 months. The study started in May 2023 and ended in April 2024.

What treatments did the participants take?

The participants in **Part A** took minzasolmin with or without esomeprazole by mouth. The participants in **Part B** took minzasolmin or a placebo by mouth. The placebo pills looked like minzasolmin pills, but did not have any minzasolmin in them. The researchers used the placebo to better understand what effects may have been related to minzasolmin. Doses of study treatment 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 the different forms of minzasolmin, esomeprazole, and the placebo. **Minzasolmin** is the drug that the researchers wanted to learn more about.

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

In **Part A** of this study, the participants started by taking 180 mg of minzasolmin in 3 different forms:

- As granules in capsules
- As tablets, which are pills that do not have an outer shell
- As encapsulated tablets, which are tablets inside capsules

All the participants in **Part A** took minzasolmin in all 3 different forms, but in a different order. The researchers used a computer program to randomly choose the order that each participant took the treatments.

Then, the participants took minzasolmin in these 3 different forms again. This time, they also took 40 mg of **esomeprazole** to decrease acid production in their stomachs. Esomeprazole was taken once a day as capsules by mouth.

During **Part A**, the participants took minzasolmin a total of **6 times**, with at least **4 days** between each dose. This was done to make sure study treatment could leave their bodies before they took the next treatment. The participants stayed in the clinic for about a month during this part.

Clinical Study Results

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

In **Part B** of this study, each participant took either minzasolmin or the placebo **2 times**. All the study treatments in Part B were taken as granules in capsules, but different participants took different doses of either minzasolmin or the placebo.

For Part B, the researchers used a computer program to randomly choose the doses that each participant took.

6 participants took the **placebo**:

- 2 participants took 90 mg of the placebo, followed by 180 mg of the placebo
- 2 participants took 180 mg of the placebo, followed by 360 mg of the placebo
- 2 participants took 360 mg of the placebo, followed by 90 mg of the placebo

25 participants took **minzasolmin**:

- 8 participants took 90 mg of minzasolmin, followed by 180 mg of minzasolmin
- 9 participants took 180 mg of minzasolmin, followed by 360 mg of minzasolmin
- 8 participants took 360 mg of minzasolmin, followed by 90 mg of minzasolmin

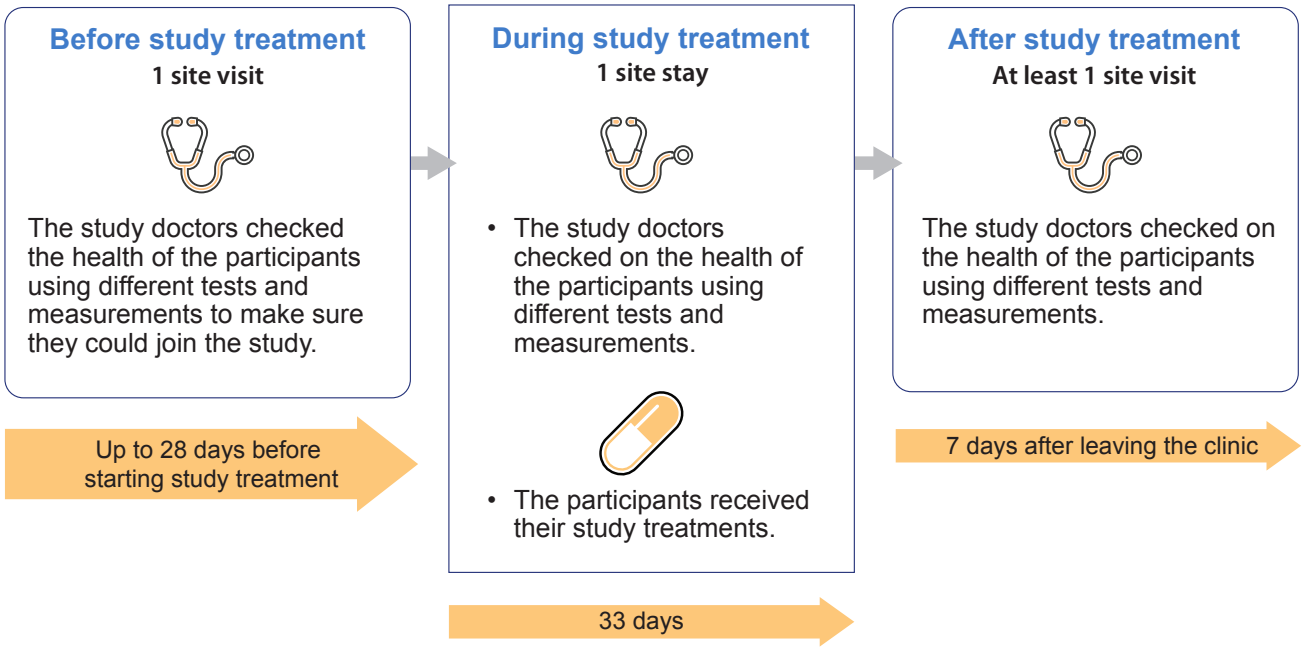
None of the participants, study doctors, or UCB staff knew what treatment the participants were taking during Part B. But a small number of site staff knew. Some studies are done this way because knowing what treatment the participants are taking can affect the results of the study.

During **Part B**, the participants took minzasolmin or the placebo a total of **2 times**, with **4 days** between each dose. The participants stayed in the clinic for 10 days during this part.

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. For each part of the study (Part A or Part B), these are the combined results from all participants in that particular part. 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 for Part B below include 30 out of 31 participants. This is because 1 Chinese participant left the study before getting their last dose.

Did the amount of acid in the stomach affect the way minzasolmin moved throughout the body over time when taken in different forms?

No. In **Part A** of this study, taking different forms of minzasolmin and taking minzasolmin with or without esomeprazole did not have a meaningful effect on the way minzasolmin moved throughout the body over time. Esomeprazole is a drug that decreases the amount of acid in the stomach.

To answer this question, the researchers measured the levels of minzasolmin in the participants' blood at different times throughout **Part A** of the study. The researchers saw some differences between the participants but concluded that these differences were not meaningful.

These results mean the researchers found that the 3 forms of minzasolmin **were not** affected by the acid production in the participants' stomachs.

There is more information about the 3 forms of minzasolmin that the participants took earlier in this summary, in the "What treatments did the participants take?" section.

How did minzasolmin move throughout the body over time in Chinese and Japanese participants?

In **Part B** of this study, minzasolmin moved throughout the body over time in a similar way in Chinese and Japanese participants.

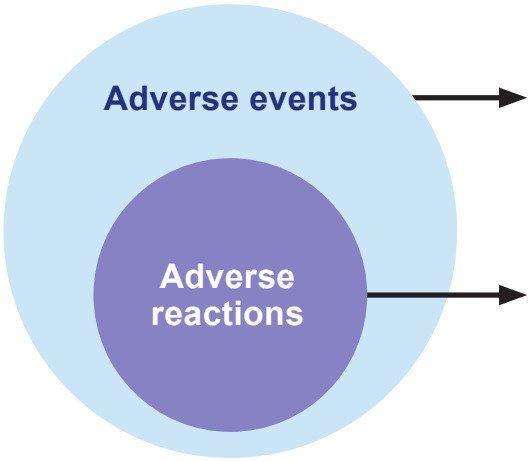
To answer this question, the researchers measured the levels of minzasolmin in the participants' blood at different times throughout Part B of the study. **Part B** of the study included only Chinese and Japanese participants.

One participant left the study before getting their last dose. So, this participant's results for the last dose were not used to answer this question.

What medical problems did Chinese and Japanese participants have 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 study treatment. An **adverse reaction** is different from an adverse event because it is reported by the doctor as **possibly related** to 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



Adverse events are all of the medical problems the participants had during this study

Adverse reactions are medical problems the participants had during this study that the study doctors reported as possibly related to study treatment

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

There were 29.0% of participants (9 of 31) who had an adverse event in this study.

Adverse events in **Part B** of this study

	Japanese participants (out of 15 participants)	**Chinese participants** (out of 16 participants)
How many participants had **serious** adverse events?	none 	none 
How many participants had adverse events?	20.0% (3 participants) 	37.5% (6 participants) 
How many participants left the study due to adverse events?	none 	none 

The most common adverse events were headache and skin redness (Erythema).

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?

Adverse reactions in this study

	Part A: all participants (out of 42 participants)	**Part B: Japanese participants** (out of 15 participants)	**Part B: Chinese participants** (out of 16 participants)
How many participants had **serious** adverse reactions?	none	none	none
How many participants had adverse reactions?	40.5% (17 participants)	20.0% (3 participants)	25.0% (4 participants)
How many participants left the study due to adverse reactions?	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 reaction in **Part A** was headache.

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

Adverse reactions in 2 or more participants in Part A

Adverse reaction	**Part A: all participants** (out of 42 participants)
Headache	11.9% (5)
Constipation	9.5% (4)
Dizziness	7.1% (3)
Acne	7.1% (3)
Abnormal dreams	4.8% (2)

The most common adverse reactions in **Part B** were headache and skin redness (Erythema).

The table below shows all the adverse reactions that happened in Part B of this study.

Adverse reactions in the participants in Part B

Adverse reaction	**Part B: Japanese participants** (out of 15 participants)	**Part B: Chinese participants** (out of 16 participants)
Headache	6.7% (1)	6.3% (1)
Skin redness (Erythema)	none	12.5% (2)
Constipation	6.7% (1)	none
Increased levels of transaminase in the blood, which may be a sign of liver injury	6.7% (1)	none
Feeling weak or lacking energy (Asthenia)	none	6.3% (1)
Chest discomfort	none	6.3% (1)
Dizziness	none	6.3% (1)
Itchy skin (Pruritus)	none	6.3% (1)
Nausea	none	6.3% (1)
Stomach pain	none	6.3% (1)

What did the researchers learn from this study?

The results of this study have helped researchers learn more about how minzasolmin moves throughout the body over time and about its safety.

In this study, the researchers found that:

- Taking minzasolmin as granules in capsules, as tablets, or as encapsulated tablets did not affect the way minzasolmin moved throughout the body over time.
- The acid production in a participant's stomach did not affect the way minzasolmin moved throughout the body over time.
- Minzasolmin moved throughout the body over time in a similar way in Chinese and Japanese participants.
- There were 40.5% of participants in Part A (17 out of 42) who had adverse reactions. The most common adverse reaction in Part A was headache.
- There were 22.6% of participants in Part B (7 out of 31) who had adverse reactions. The most common adverse reactions in Part B were headache and skin redness (Erythema).

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:

- www.clinicaltrials.gov/ct2/show/study/NCT05845645

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

Study Information

Protocol Number: UP0073

National Clinical Trial Number: NCT05845645

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

Full Study Title: A 2-Part Study to Evaluate the Relative Bioavailability of 2 New Formulations of UCB0599 and the Effect of Esomeprazole on the PK of UCB0599 in Healthy Participants (Part A, Open-Label) and to Assess the Safety/Tolerability and PK of UCB0599 in Healthy Participants of Japanese and Chinese Origins (Part B, Double-Blind)

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 17 April 2025.
The final clinical study report is dated 24 September 2024.