
Study Sponsor: UCB Biopharma SRL

Drug Studied: Brivaracetam

Protocol Number: EP0231

Short Study Title: A study to learn more about how 2 different forms of brivaracetam move throughout the body over time in healthy Japanese males

Thank you

UCB thanks all the participants of this study. All the participants helped the researchers learn more about the safety of brivaracetam.

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 03 June 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 certain types of seizures in Japanese people. 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 treatment did the participants take?

The participants in this study took brivaracetam in 2 different forms:



- By mouth as a **tablet**
 - By mouth as a **dry syrup**
 - A dry syrup consists of a packet of powdered brivaracetam that is mixed into water and then taken by mouth
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What were the results of this study?

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



- **Did brivaracetam move throughout the body over time similarly when taken as a dry syrup compared to when taken as a tablet?**
Yes. Overall, the researchers found that brivaracetam moved throughout the participants' bodies in about the same way when they took it as a dry syrup compared to when they took it as a tablet.

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 10.9% of participants (7 out of 64) who had medical problems that the study doctors reported as **possibly related** to study treatment. The most common possibly related medical problems were dizziness and feeling sleepy (Somnolence).

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 how the dry syrup form of brivaracetam moved throughout the bodies of healthy Japanese males compared to the tablet form of brivaracetam, and if they had any medical problems during the study. This information is important to know before additional studies can be done that help find out if brivaracetam can improve the health of people living with focal seizures.

A “healthy participant” is someone who does not have the condition the treatment is trying to treat or other serious health conditions.

People with epilepsy can have seizures. Seizures are caused by uncontrolled electrical activity in the brain. Some seizures start in just 1 part of the brain. These are called **focal seizures**. Focal seizures are also called partial or partial-onset seizures. Sometimes focal seizures can spread to both sides of the brain.

Treatments exist for focal seizures, but they may not work well enough for everyone. The study drug **brivaracetam** is designed to help reduce the number of seizures. Brivaracetam is currently approved in many countries around the world to treat people who have focal seizures.

Brivaracetam is often taken as a tablet, but for younger people who need different doses based on their body weight or people who cannot swallow a tablet, a dry syrup form of brivaracetam was developed. Before the dry syrup form of brivaracetam can be used by patients, researchers want to make sure it works similarly to the tablet form.

Treatments may work differently for people of different ethnicities or races. In this study, the researchers wanted to learn more about the safety of brivaracetam in healthy Japanese males.



What was the main question studied?

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

- Did brivaracetam move throughout the body over time similarly when taken as a dry syrup compared to when taken as a tablet?

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



Who participated in the study?

There were 64 healthy males of Japanese descent who participated in this study. They were 20 to 50 years old when they joined.

The study included participants in 1 country.



Each participant who completed the study was in the study for about 2 months. The whole study lasted 3 months. The study started in March 2024 and ended in June 2024.



What treatments did the participants take?

The participants in this study took **brivaracetam** in **2 different forms**:

- By mouth as a **tablet**
- By mouth as a **dry syrup**

Doses of both forms of brivaracetam were measured in milligrams, also called mg.

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

All the participants took both forms of brivaracetam, but in a different order. This helps researchers see how each treatment works in each participant.

The researchers used a computer program to randomly choose the order that each participant took the 2 forms of brivaracetam. This helped make sure the treatments were chosen fairly and comparing the results for the treatments was as accurate as possible.

In between taking each treatment, the participants stopped taking any study treatment for up to 10 days. This part is called a “washout period”. This was done to make sure the treatment could leave their bodies before they took the next treatment.

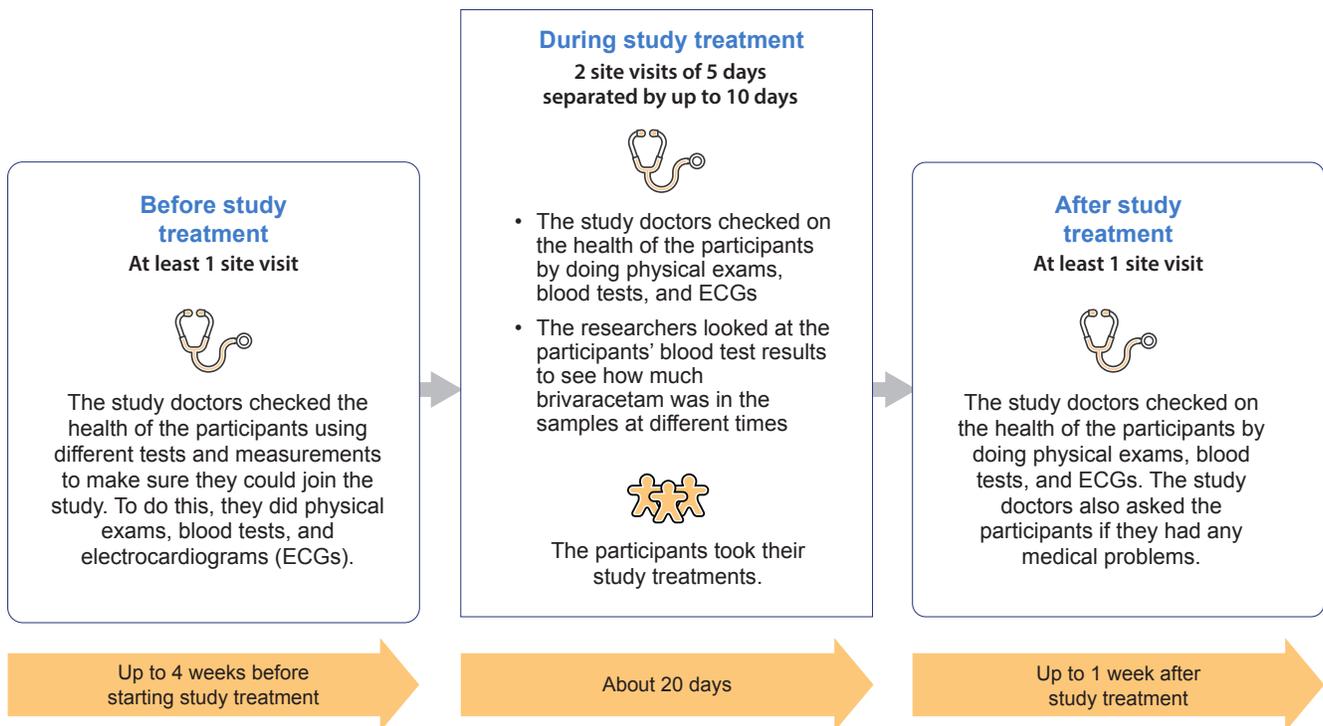
The chart below shows the treatments the researchers studied:

	Treatment A	Treatment B
	64 participants	
	50 mg of brivaracetam as a tablet	50 mg of brivaracetam as a dry syrup
	Twice a day for 2 days, then once in the morning on the third day	

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 brivaracetam move throughout the body over time similarly when taken as a dry syrup compared to when taken as a tablet?

Yes. Overall, the researchers found that brivaracetam moved throughout the participants' bodies in about the same way when they took it as a dry syrup compared to when they took it as a tablet.

The researchers answered this question by measuring the levels of brivaracetam in the participants' blood at different times during each 5-day site visit. Then, they compared the results from when the participants took brivaracetam as a dry syrup to when they took brivaracetam as a tablet.



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**".

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.

Clinical Study Results

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.

There was 1 participant who left the study before taking brivaracetam as tablets. So, the results for **brivaracetam as a tablet** below only include 63 participants.

Did any adverse reactions happen during this study?

There were 10.9% of participants (7 out of 64) who had an adverse reaction in this study.

Adverse reactions in this study

	Brivaracetam as a tablet (out of 63 participants)	Brivaracetam as a dry syrup (out of 64 participants)
How many participants had serious adverse reactions?	none	none
How many participants had adverse reactions?	 3.2% (2 participants)	 9.4% (6 participants)
How many participants left the study due to adverse reactions?	none	none

What adverse reactions did the participants have?

The most common adverse reactions were dizziness and feeling sleepy (Somnolence). The table below shows all the adverse reactions that happened in this study.

Adverse reaction	Brivaracetam as a tablet (out of 63 participants)	Brivaracetam as a dry syrup (out of 64 participants)
Dizziness	3.2% (2)	4.7% (3)
Feeling sleepy (Somnolence)	1.6% (1)	4.7% (3)
Feeling tired (Fatigue)	none	1.6% (1)
Headache	none	1.6% (1)

What did the researchers learn from this study?

The results of this study have helped researchers learn more about how brivaracetam moves throughout the body in healthy Japanese males. In this study, the researchers found that:

- Brivaracetam moved throughout the participants' bodies in about the same way when taken as a dry syrup compared to when taken as a tablet.
- There were 10.9% of participants (7 out of 64) who had medical problems that the study doctors reported as possibly related to the study drug. The most common possibly related medical problems were dizziness and feeling sleepy (Somnolence).

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 health or situation, please contact your doctor.

At the time this document was approved, further clinical studies with brivaracetam were ongoing.



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/NCT06312566

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

Study Information

Protocol Number: EP0231

National Clinical Trial Number: NCT06312566

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

Full Study Title: A Multiple-Dose, Open-Label, Randomized, 2-Way Cross-Over Study to Assess the Bioequivalence Between Brivaracetam Tablet and Dry Syrup in Healthy Male Japanese 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 03 June 2025.
The final clinical study report is dated 18 October 2024.