Clinical Study Results

Inspired by patients. Driven by science.

Study Sponsor: UCB Biopharma SRL

Treatment Studied: Brivaracetam

Protocol Number: EP0085

Study Purpose: A study to learn more about the safety of brivaracetam in Japanese and Chinese teenagers and adults with focal seizures

Thank you

UCB thanks all the participants of this study and their caregivers. All the participants and caregivers 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, their caregivers, 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 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 way to treat focal seizures in Japanese and Chinese teenagers and adults. 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.

What were the results of this study?

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

- **What medical problems did the participants have during this study?**

  There were 93.7% of participants (194 out of 207) who had medical problems during this study. The most common medical problem was COVID-19.

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 35.7% of participants (74 out of 207) who had medical problems that the study doctors reported as **possibly related** to study treatment. The most common possibly related medical problem was 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 if brivaracetam worked in a large number of Japanese and Chinese participants living with focal seizures. They also wanted to learn if the participants had any medical problems during the study.

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. There are other types of seizures called generalized seizures that happen in both sides of the brain at once.

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 some parts of the world to treat patients aged 1 month or older who have focal seizures.

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 Japanese and Chinese participants.

What was the main question studied?

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

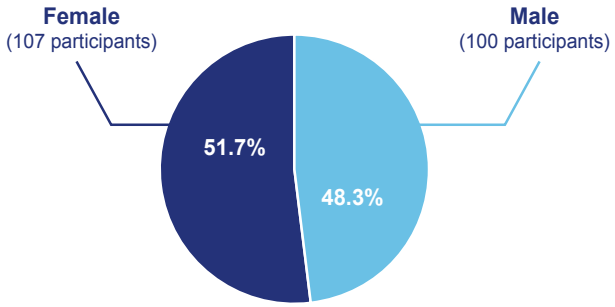
- What medical problems did the participants have during this study?

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

Who participated in the study?

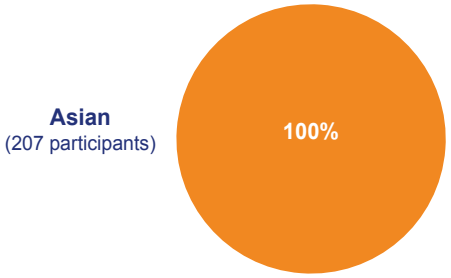
There were 207 participants with focal seizures who participated in this study. They were 16 to 91 years old when they joined.

Sex
(out of 207 participants)



Percentage of participants (%)

Race
(out of 207 participants)



Percentage of participants (%)

Ethnicity
(out of 207 participants)

Japanese, 63.3% (131 participants)

Chinese, 36.2% (75 participants)

Other, 0.5% (1 participant)

Clinical Study Results

The study included participants in 2 countries.

In this study, the researchers included participants living with focal seizures who either:

- Had previously completed treatment in a study called EP0083 or had been participating in a study called N01379, which were both studies of brivaracetam

or

- Had 1 to 8 focal seizures in the 2 months (8 weeks) before starting this study

In China, each participant who completed the study was in the study for a little more than 2 years.

In Japan, each participant who completed the study was in the study until brivaracetam was approved in Japan. The whole study lasted a little more than 7 years. The study started in August 2017 and ended in December 2024.

What treatment did the participants take?

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

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

At the beginning of the study, participants who were not coming from study EP0083 or N01379 started at a lower dose of brivaracetam that could be increased depending on how it was working for them.

Of the 207 participants in this study:

- 166 came from EP0083
- 7 came from N01379
- 34 did not participate in either EP0083 or N01379

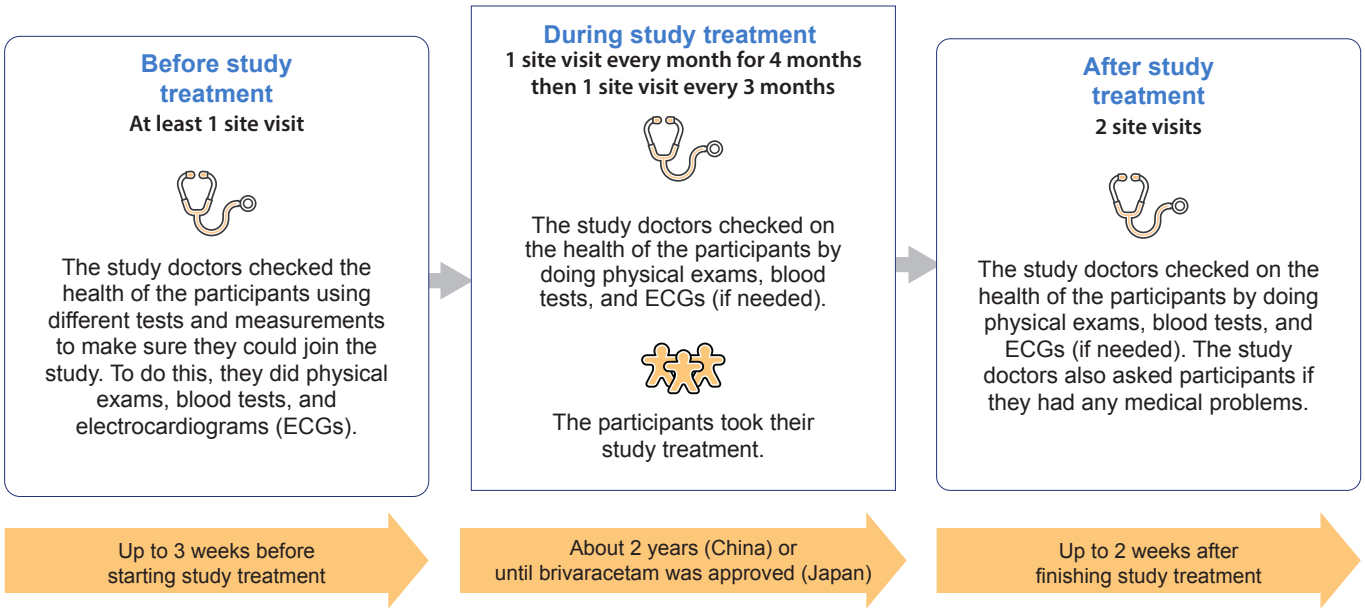
The chart below shows the treatment plan for this study:

	Brivaracetam
	207 participants
	Up to 200 mg of brivaracetam
	China: twice a day for up to 2 years **Japan**: until brivaracetam was approved or the study ended

What happened during this study?

Each participant or their parents or caregivers first learned about the study and then decided to join the study or to let the participant join. This process is called “informed consent”.

The chart below shows what happened in this study for each participant:



What were the results of the study?

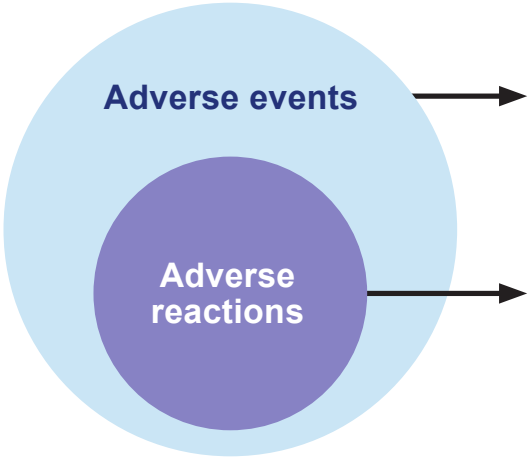
This is a summary of the main results from this study. These are the results from all the participants combined. The individual results of each participant might be different and are not in this summary.

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.

What medical problems did the 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.

Clinical Study Results

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

There were 93.7% of participants (194 of 207) who had an adverse event in this study.

	Brivaracetam (out of 207 participants)
How many participants had **serious** adverse events?	19.3% (40 participants) 
How many participants had adverse events?	93.7% (194 participants) 
How many participants left the study due to adverse events?	4.8% (10 participants) 

The most common **serious** adverse events were:

- Worsening epilepsy
- Brain operation
- Headache
- Suicide attempt
- A lung infection called pneumonia caused by inhaling food or liquid

The most common adverse events were:

- COVID-19
- Common cold (Nasopharyngitis)
- Dizziness
- Fever

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.

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 of the adverse reactions listed below may also be listed in the adverse events section earlier in this summary.

Did any adverse reactions happen during this study?

There were 35.7% of participants (74 of 207) who had an adverse reaction in this study.

Adverse reactions in this study

	Brivaracetam (out of 207 participants)
How many participants had **serious** adverse reactions?	2.4% (5 participants) 
How many participants had adverse reactions?	35.7% (74 participants) 
How many participants left the study due to adverse reactions?	3.9% (8 participants) 

What serious adverse reactions did the participants have?

The table below shows the serious adverse reactions that happened during the study. Some of the participants had more than 1 serious adverse reaction.

Serious adverse reaction	**Brivaracetam** (out of 207 participants)
Accidentally taking too much study drug	0.5% (1)
Stroke	0.5% (1)
Dizziness	0.5% (1)
Abnormal growth on the gallbladder	0.5% (1)
Headache	0.5% (1)
Having a tremor, slow movements, and other symptoms like Parkinson's disease	0.5% (1)
Vomiting	0.5% (1)

None of the participants died due to adverse reactions.

What adverse reactions did the participants have?

The most common adverse reaction was feeling sleepy (Somnolence).

The table below shows the adverse reactions that happened in 2.0% or more of all participants. There were other adverse reactions, but those happened in fewer participants.

Adverse reaction	**Brivaracetam** (out of 207 participants)
Feeling sleepy (Somnolence)	10.1% (21)
Dizziness	5.3% (11)
Irritability	2.9% (6)
Decreased appetite	2.4% (5)
Seizure	2.4% (5)

What did the researchers learn from this study?

The results of this study have helped researchers learn more about using brivaracetam in Japanese and Chinese people living with focal seizures. In this study, the researchers found that:

- There were 93.7% of participants (194 out of 207) who had medical problems during this study. The most common medical problem was COVID-19.
- There were 35.7% of participants (74 out of 207) who had medical problems that the study doctors reported as possibly being related to study treatment. The most common possibly related medical problem was 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 or your child's health or situation, please contact your doctor.

At the time this document was approved, further clinical studies in focal seizures 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/NCT03250377

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

Study Information

Protocol Number: EP0085

National Clinical Trial Number: NCT03250377

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

Full Study Title: An Open-Label, Multicenter, Follow-Up Study To Evaluate The Long-Term Safety And Efficacy Of Brivaracetam Used As Adjunctive Treatment In Subjects ≥16 Years Of Age With Partial Seizures With Or Without Secondary Generalization

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 17 June 2025.
The final clinical study report is dated 06 May 2025.