Clinical Study Results

Inspired by patients. Driven by science.

Study Sponsor: UCB Biopharma SRL

Drug Studied: Brivaracetam

Protocol Number: EP0132

Study Purpose: A study to learn about the safety of long-term treatment with brivaracetam in children and young adults with childhood or juvenile absence epilepsy

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 13 August 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 childhood and juvenile absence epilepsy. 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 treatments 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 45.2% of participants (38 out of 84) who had medical problems during this study.

  The most common medical problem was seizures that may often cause a few seconds of blank staring or loss of consciousness (Absence seizures).

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 7.1% of participants (6 out of 84) who had medical problems that the study doctors reported as **possibly related** to study treatment. The most common possibly related medical problems were headache, feeling sleepy (Somnolence), and thinking about suicide (Suicidal ideation).

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?

The researchers in this study wanted to learn how safe brivaracetam was in participants living with childhood absence epilepsy (**CAE**) or juvenile absence epilepsy (**JAE**).

CAE and JAE are brain disorders that cause a type of seizure called absence seizures. **Absence seizures** can be different for each person but often cause a few seconds of blank staring and loss of consciousness.

People with CAE can have absence seizures many times a day, which can make it hard for them to do everyday activities or pay attention in school. CAE may get better as the child gets older. JAE seizures may happen less than once a day, but JAE is often a life-long condition.

There are currently some treatments for CAE and JAE. However, for some people, these treatments may not work or may cause medical problems. The study drug **brivaracetam** is designed to help reduce the uncontrolled electrical activity in the brain that causes seizures. Brivaracetam is currently approved in the United States to treat people aged 1 month and older who have another type of seizure called partial onset seizures (also known as focal onset seizures). It is also approved in other countries to treat people aged 2 years and older who have partial onset seizures.

In this study, the researchers wanted to learn about the long-term safety of brivaracetam in children and young adults with CAE or JAE. All the participants in this study had taken brivaracetam in a study called N01269, which was still ongoing at the time this summary was written.

What was the main question studied?

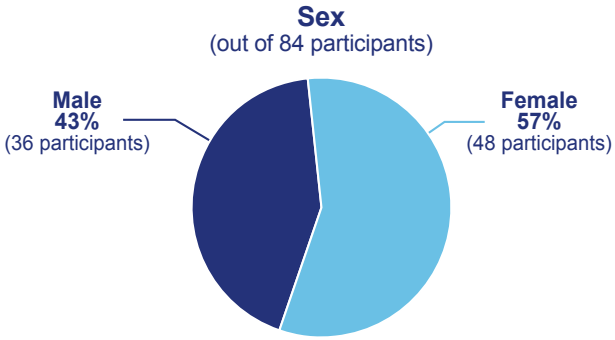
The main question the researchers wanted to answer in this study was:

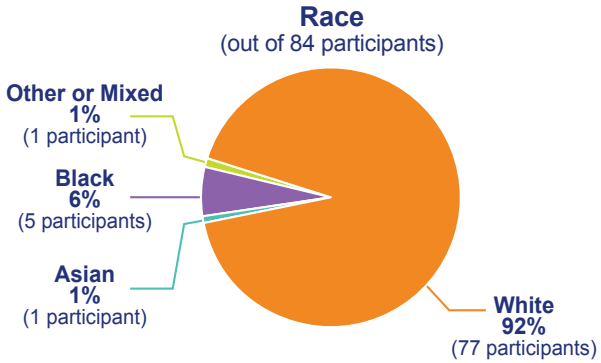
- What medical problems did the participants have during this study?

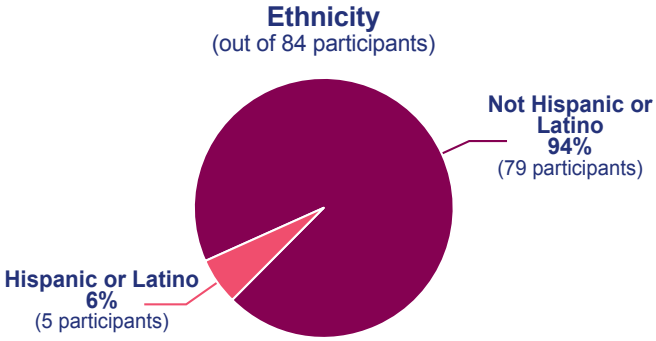
The researchers also wanted to know what medical problems happened that were possibly related to study treatment.

Who participated in the study?

There were 84 participants with CAE or JAE who participated in this study. They were 4 to 17 years old when they joined.

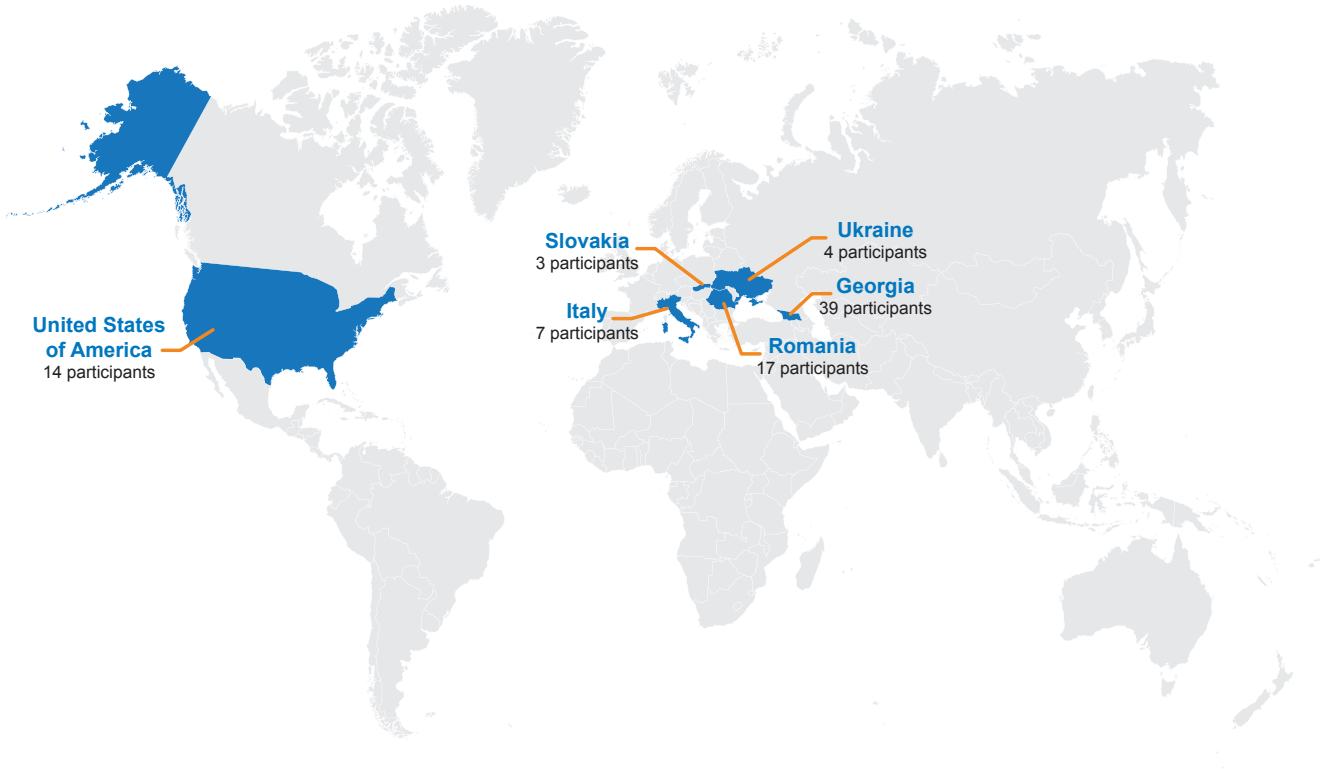






Clinical Study Results

The study included participants in 6 countries.



In this study, the researchers included participants living with CAE or JAE who:

- Had participated in another brivaracetam study called the N01269 study
- Were expected to benefit from taking brivaracetam over a long period of time, according to the study doctors

The participants who completed this study were in the study for 1 to 31 months (about 2 and a half years). The study started in March 2022 and ended in March 2025.

What treatments 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, the participants who weighed 50 kg or more started taking 50 mg of brivaracetam twice a day. This dose could be increased or decreased depending on how it was working for them.

Participants who weighed less than 50 kg took different doses that were adjusted to their body weight.

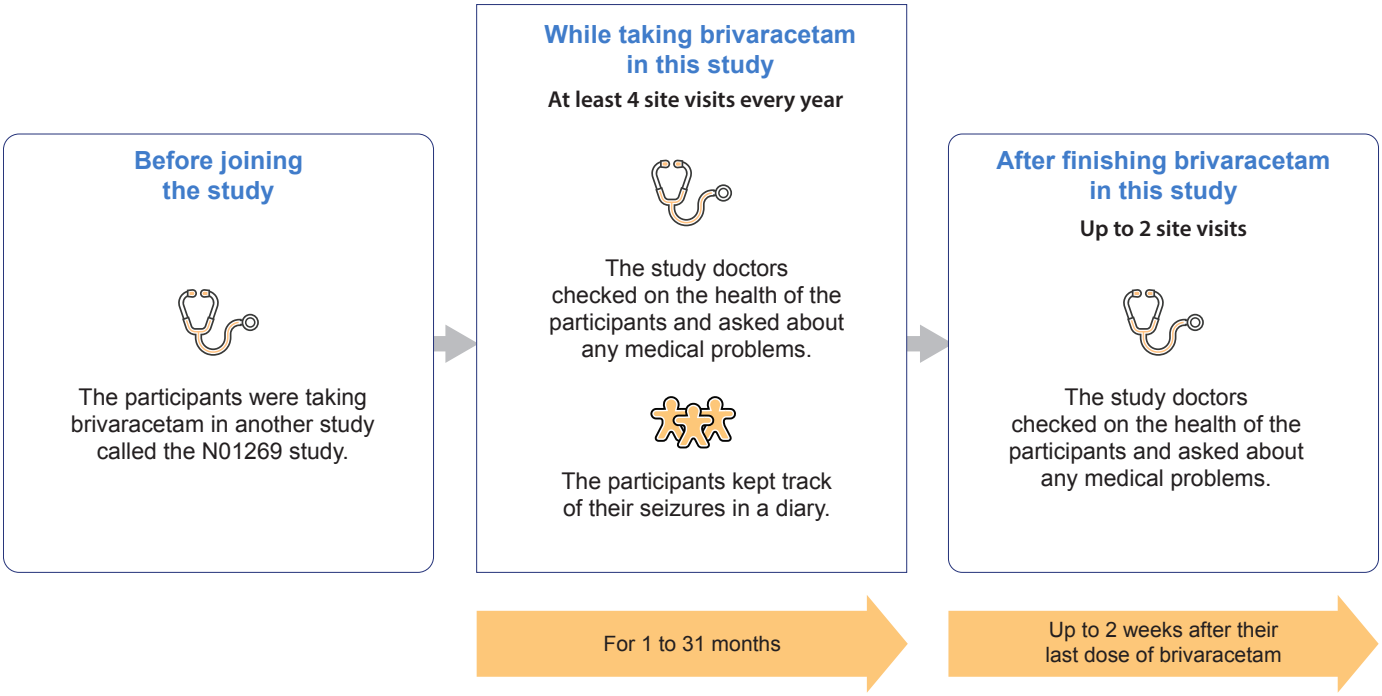
The chart below shows the treatments the researchers studied.

	CAE	JAE
	64 participants	20 participants
	Brivaracetam as a tablet or as a liquid by mouth	
	Until another study was available to allow continued treatment with brivaracetam, the study ended, or they left the study for another reason	

What happened during this study?

Each participant, or their parent or caregiver, learned about the study and decided to join the study or to let the participant join the study in a process called “informed consent”.

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



At the end of this study, the participants were given the option to continue taking brivaracetam as part of another study or a post-trial access program.

What were the results of the study?

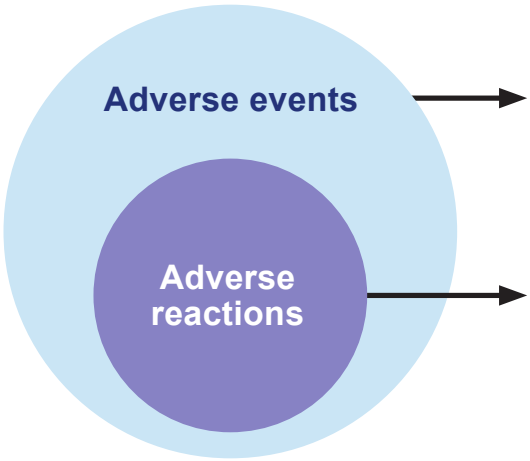
This is a summary of the main results from this study. These are the results from all the participants combined. The individual results of each participant might be different and are not in this summary.

Deciding which treatments work best often 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.

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

There were 45.2% of participants (38 of 84) who had an adverse event in this study.

Adverse events in this study

	CAE (out of 64 participants)	JAE (out of 20 participants)
How many participants had **serious** adverse events?	3.1% (2 participants) 	10.0% (2 participants) 
How many participants had adverse events?	42.2% (27 participants) 	55.0% (11 participants) 
How many participants stopped taking study treatment due to adverse events?	3.1% (2 participants) 	10.0% (2 participants) 

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

- Infected lymph nodes (Lymphadenitis)
- A viral infection that causes symptoms including a cough, runny nose, and skin rash (Measles)
- Seizures that cause uncontrollable shaking of the whole body (Generalized tonic-clonic seizure)
- Seizures that last too long or happen back to back (Status epilepticus)
- Thinking about suicide (Suicidal ideation)

The most common adverse event was seizures that may often cause a few seconds of blank staring or loss of consciousness (Absence seizures).

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.

Some of the adverse reactions listed below may also be listed in the adverse events section earlier in this summary. Some participants had more than 1 adverse reaction.

Did any adverse reactions happen during this study?

There were 7.1% of participants (6 out of 84) who had at least one adverse reaction in this study.

Adverse reactions in this study

	CAE (out of 64 participants)	**JAE** (out of 20 participants)
How many participants had **serious** adverse reactions?	1.6% (1 participant) 	none 
How many participants had adverse reactions?	6.3% (4 participants) 	10.0% (2 participants) 
How many participants stopped taking study treatment due to adverse reactions?	3.1% (2 participants) 	5.0% (1 participant) 

What serious adverse reactions did the participants have?

The serious adverse reaction that happened during this study was thinking about suicide (Suicidal ideation). This serious adverse reaction happened in 1 participant with CAE.

None of the participants died due to serious adverse reactions.

What adverse reactions did the participants have?

The most common adverse reactions were:

- Headache
- Feeling sleepy (Somnolence)
- Thinking about suicide (Suicidal ideation)

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

Adverse reactions in this study

Adverse reaction	CAE (out of 64 participants)	JAE (out of 20 participants)
Headache	1.6% (1)	5.0% (1)
Thinking about suicide (Suicidal ideation)	1.6% (1)	5.0% (1)
Difficulty paying attention	1.6% (1)	none
Difficulty speaking (Dysarthria)	1.6% (1)	none
Hives	1.6% (1)	none
Feeling sleepy (Somnolence)	none	10.0% (2)
Feeling weak or lacking energy (Asthenia)	none	5.0% (1)
Having a sudden feeling of spinning or being off balance (Vertigo)	none	5.0% (1)
Nausea	none	5.0% (1)

What did the researchers learn from this study?

The results of this study have helped researchers learn more about using brivaracetam over a long period of time in children and young adults living with CAE or JAE. In this study, the researchers found that:

- There were 45.2% of participants (38 out of 84) who had adverse events. The most common adverse event was seizures that may often cause a few seconds of blank staring or loss of consciousness (Absence seizures).
- There were 7.1% of participants (6 out of 84) who had adverse reactions. The most common adverse reactions were headache, feeling sleepy (Somnolence), and thinking about suicide (Suicidal ideation).

Deciding which treatments work best for patients often 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 brivaracetam were ongoing.

Where can I learn more about this study?

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

- www.clinicaltrials.gov/study/NCT05109234
- https://www.clinicaltrialsregister.eu/ctr-search/search?query=2020-002769-33

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

Study Information

Protocol Number: EP0132

National Clinical Trial Number: NCT05109234

EudraCT Number: 2020-002769-33

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

Full Study Title: A Multicenter, Open-Label, Single-Arm Study to Evaluate Long-Term Safety, Tolerability, and Efficacy of Brivaracetam in Study Participants 2 to 26 Years of Age With Childhood Absence Epilepsy or Juvenile Absence Epilepsy

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 13 August 2025.
The final clinical study report is dated 16 July 2025.