Clinical Study Results

Inspired by patients. Driven by science.

Study Sponsor: UCB Biopharma SRL

Drug Studied: Lacosamide

Protocol Number: EP0151

Study Purpose: A study to learn if lacosamide is safe to take over a long period of time in children with 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 lacosamide.

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 and their caregivers 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 18 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 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 lacosamide as a syrup by mouth.

What were the results of this study?

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

- **What medical problems did the participants have during this study?**
  There were 39.6% of participants (19 of 48) who had a medical problem during this study. The most common medical problem was nose and throat infection (Upper respiratory tract infection).
- **What daily doses of lacosamide did the participants take?**
  The most common dose that the participants took was 10 milligrams per kilogram per day. This was also the most common **highest** daily dose that the participants took.

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 no participants who had medical problems that the study doctors reported as **possibly related** to study treatment.

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 more about lacosamide for young participants living with epilepsy. They also wanted to learn if the participants had any medical problems during the study.

Researchers are looking for a better way to treat epilepsy. **Epilepsy** is a brain disorder that causes seizures. The symptoms of seizures can be different for each person but can include uncontrollable shaking and loss of consciousness.

The study drug **lacosamide** is designed to work by changing the electrical activity in the brain to help prevent seizures.

Lacosamide is approved as a treatment for adults and children with a certain type of seizure disorder called partial-onset seizures. Research is currently ongoing to learn more about using lacosamide to treat epilepsy in both adults and children.

In this study, the researchers wanted to find out if lacosamide is safe for children under the age of 6 with epilepsy to take over a long period of time. All the participants in this study had taken lacosamide in 1 of 2 previous studies, which were called EP0034 and SP848.

What were the main questions studied?

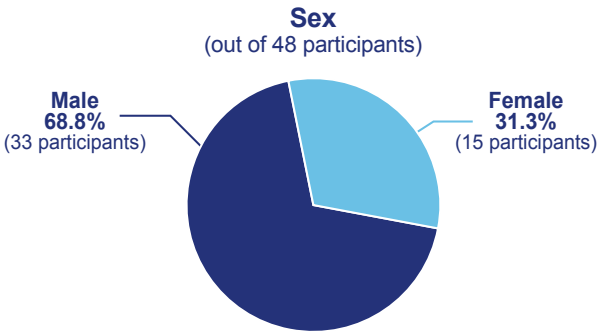
The main questions the researchers wanted to answer in this study were:

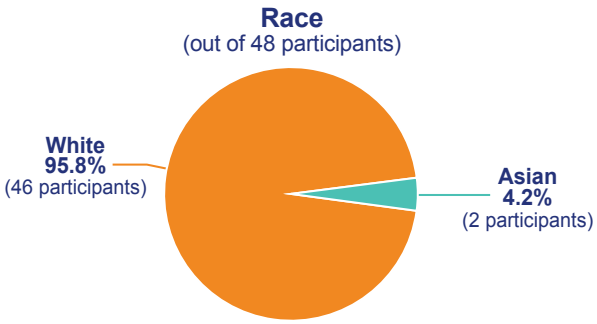
- What medical problems did the participants have during this study?
- What daily doses of lacosamide did the participants take?

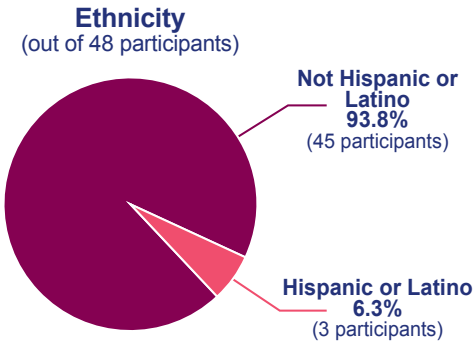
The researchers also wanted to know what medical problems happened that were possibly related to study treatment.

Who participated in the study?

There were 48 participants with epilepsy who participated in this study. They were 2 to 5 years old when they joined.







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The study included participants in 6 countries.

In this study, the researchers included children living with epilepsy who:

- Had received lacosamide in 1 of 2 other studies called EP0034 and SP848
- Were expected to benefit from taking lacosamide over a long period of time according to study doctors

Participants who completed the study were in the study for up to a little more than 4 years. The study started in December 2020 and ended in February 2025.

What treatments did the participants take?

The participants in this study took lacosamide. Doses of lacosamide were measured in milligrams per kilogram of each participant's weight, also called mg/kg.

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

Throughout the study, doctors were able to change the dose of lacosamide that each participant took, based on what they thought was best for the participant at that time. If study doctors and a participant's caregivers decided that the participant should stop taking lacosamide, the dose of lacosamide was slowly decreased until the participant stopped taking it.

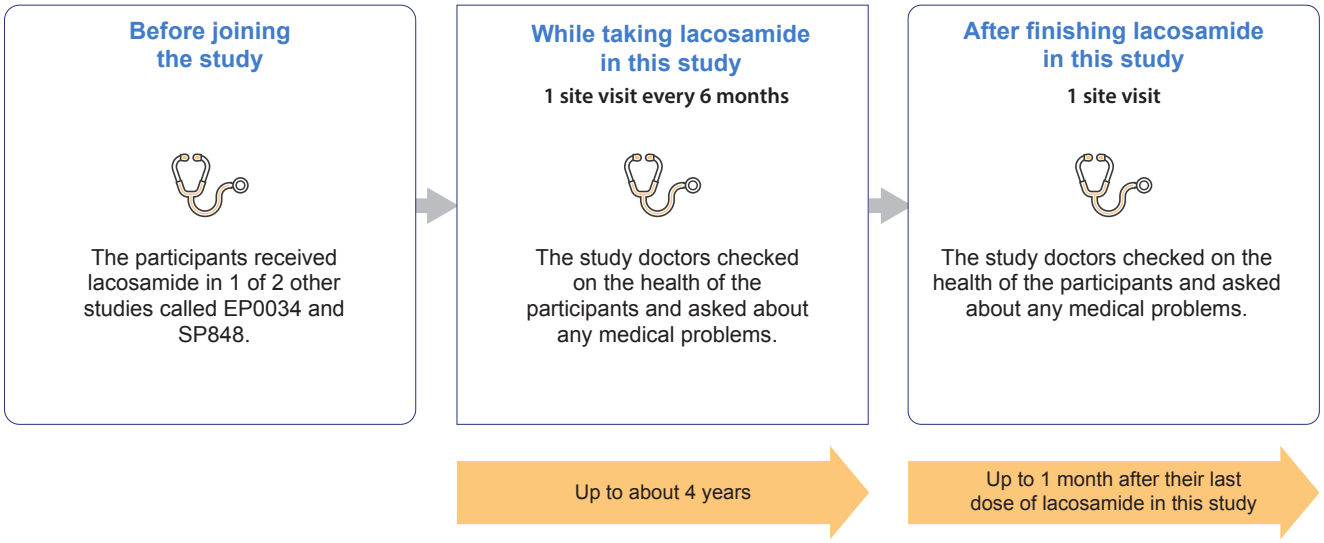
The chart below shows the treatment the researchers studied:

	48 participants
	Lacosamide taken as a syrup by mouth
	A minimum of 2 mg/kg per day, and a maximum of 12 mg/kg (or 600 mg if that was a lower dose) per day
	Until one of the following happened: • The study ended. • The participant turned 6 years of age, unless study doctors thought they would benefit from continuing in the study. • Lacosamide oral solution (syrup) became available for the participant in their country. • The participant stopped taking lacosamide for any reason.

What happened during this study?

Each participant's parent or caregiver learned about the study and decided 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:



What were the results of this study?

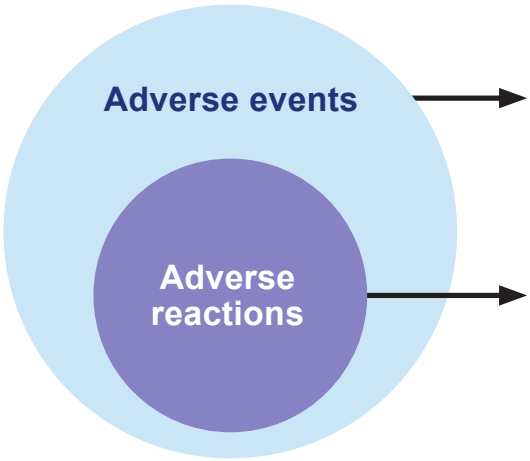
This is a summary of the main results from this study. These are the results from all the participants combined. The individual results of each participant might be different and are not in this summary.

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 think may be 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.

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

There were **39.6%** of participants (19 of 48) who had an adverse event in this study.

	Lacosamide (out of 48 participants)
How many participants had **serious** adverse events?	14.6% (7 participants) 
How many participants had adverse events?	39.6% (19 participants) 
How many participants left the study due to adverse events?	4.2% (2 participants) 

There were 13 **serious** adverse events that each happened in 1 participant. Participants may have had more than 1 serious adverse event each. The serious adverse events were:

- Sudden heart failure
- An abnormally developed hip (Developmental hip dysplasia)
- Medical device stops working properly
- Dying suddenly
- An infection in the airways of the lungs (Bronchopneumonia)
- A type of lung infection called pneumonia
- Pneumonia that led to damaged lung tissue
- Common cold caused by a virus called rhinovirus
- Very low blood pressure in response to an infection that can lead to organ failure (Septic shock)
- An infection from a virus
- A type of seizure called an epileptic spasm
- Seizure that starts in one side of the brain and spreads
- Sudden lung failure

The most common adverse events were:

- Nose and throat infection (Upper respiratory tract infection)
- Sore throat
- Constipation
- Vomiting
- Runny nose

What daily doses of lacosamide did the participants take?

To answer this question, the researchers kept track of the doses of lacosamide that each participant took throughout the study. The researchers specifically kept track of the following:

- The **most common** dose of lacosamide that each participant took (this is also known as the **modal dose**).
- The **highest dose** of lacosamide that each participant took (this is also known as the **maximum dose**).

The researchers summarized these results using a **median**. The median is the middle number in a set of numbers when ordered from lowest to highest.

- The median **most common dose** of lacosamide that the participants took was **10 mg/kg per day**.
- The median **highest dose** of lacosamide that the participants took was also **10 mg/kg per day**.

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**".

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?

No adverse reactions happened during this study.

What did the researchers learn from this study?

The results of this study have helped researchers learn more about using lacosamide over a long period of time in young children living with epilepsy. In this study, the researchers found that:

- There were **39.6%** of participants who had an adverse event during this study. The most common medical problem was nose and throat infection (Upper respiratory tract infection).
- No participants had an adverse event that was considered possibly related to study treatment (adverse reaction).
- The **most common dose** of lacosamide that the participants took was 10 mg/kg per day.
- The **most common highest dose** of lacosamide that participants took was also 10 mg/kg per day.

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.

When this document was approved, further clinical studies with lacosamide 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/ct2/show/study/NCT04627285
- euclinicaltrials.eu/ctis-public/view/2022-502639-21-00

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

Study Information

Protocol Number: EP0151

National Clinical Trial Number: NCT04627285

EU CT Number: 2022-502639-21-00

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

Full Study Title: A Multicenter, Open-Label, Follow-Up Study to Assess the Long-Term Use of Oral Lacosamide in Study Participants Who Completed EP0034 or SP848 and Received Lacosamide Treatment

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 18 July 2025.
The final clinical study report is dated 26 June 2025.