

# Clinical Study Results

This is a summary of the main results of a clinical study for the drug lacosamide.

UCB Biopharma SPRL sponsored this study and wants to share the results with the participants, their caregivers, and the public.

## Thank you!

UCB thanks all the participants of this study. All the participants and caregivers helped the researchers learn more about using lacosamide in children and teenagers with epilepsy.

We hope this summary helps the participants and their caregivers understand and feel proud of their important role in medical research.

This summary is for informational purposes only. If you or a child you care for needs medical advice, please contact your doctor or your child's doctor. If you or a child you care for participated in this study and have questions about the results, please speak with a doctor or staff at the study site.

## Why was the research needed?

Before a treatment is available to all patients, 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 lacosamide worked in a large number of children and teenagers with epilepsy who were already taking 1 to 3 anti-seizure medicines. They also wanted to learn if the participants had any medical problems during the study.

People with epilepsy have seizures that happen again and again. Seizures are caused by uncontrolled electrical activity in the brain. Some seizures start in just one part of the brain. These are called focal seizures. The participants in this study had focal seizures.

Lacosamide helps to reduce uncontrolled electrical activity in the brain that causes seizures. When this study began, lacosamide had been approved to treat focal seizures in adults with epilepsy, but not in children or teenagers.

### What were the main questions studied?

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

- How many focal seizures did the participants have during the study?
- What medical problems did the participants have during the study?

### Who participated in the study?

Girls and boys with epilepsy participated in this study. They were 4 to 16 years old.

All the participants in the study:

- were taking a steady dose of 1 to 3 anti-seizure medicines for at least 4 weeks before starting the study
- had at least 2 focal seizures in the 8 weeks before they started taking study drug

The study included 343 participants in 28 countries: Argentina, Australia, Belgium, Bulgaria, Colombia, Croatia, the Czech Republic, Estonia, Georgia, Hungary, Israel, Italy, Latvia, Lithuania, Mexico, Montenegro, Poland, the Republic of Korea, Romania, Russia, Serbia, Slovakia, Slovenia, Taiwan, Thailand, Ukraine, the United Kingdom, and the United States.

Each participant was in the study for up to 36 weeks, but the whole study lasted for about 3.5 years. The study started in August 2013 and ended in January 2017.

### What treatments did the participants take?

The participants in this study took either lacosamide or a placebo. The placebo looked like lacosamide, but it did not have any lacosamide in it. The researchers used a placebo so they could compare the effect of lacosamide with the placebo.

All participants also took their usual 1 to 3 anti-seizure medicines.

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The participants took either lacosamide twice each day or a placebo twice each day. For participants who weighed less than 50 kilograms, the dose of lacosamide they took was based on how much they weighed. Doses were measured in milligrams per kilogram of body weight, also called mg/kg. The daily doses were:

- 8 to 12 mg/kg of lacosamide for the participants who weighed less than 30 kg
- 6 to 8 mg/kg of lacosamide for the participants who weighed 30 kg to less than 50 kg

Participants who weighed 50 kg or more got a daily dose of 300 to 400 mg of lacosamide.

The participants who weighed less than 50 kg drank a liquid form of the study drug.

The participants who weighed 50 kg or more could drink the liquid form or take the study drug in pill form. This was based on which form was easier for them to take.

The researchers used a computer program to randomly choose if the participants took lacosamide or the placebo. This helped make sure the treatments were chosen fairly and comparing the results of the treatments was as accurate as possible.






This was a “double-blind” study. This means none of the participants, study doctors, or study staff knew what treatment each participant was taking. UCB also did not know. Some studies are done this way because knowing what treatment the participants are taking can affect the results of the study. After the study was completed, UCB learned what treatment each participant took so they could create a report of the results.

### What happened during the study?

Before the study started, each participant’s parent or caregiver learned about the study and decided to let the participant join the study. This is called “informed consent.” The study doctors and study staff then asked about the participant’s medical history and checked the participant’s health to make sure they could join the study.

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During the study:

	The participants or their caregivers kept track of their seizures every day using diaries.
	The participants gave blood and urine samples at some clinic visits.
	The participants had electrocardiograms, also called ECGs. ECGs are tests that record electrical activity in the heart.
	The study doctors kept track of any medical problems reported by the participants or observed by the caregivers, study doctors, or study staff.
	The participants kept taking their usual 1 to 3 anti-seizure medicines.

There were 3 main parts of the study.

**Part 1 lasted 8 weeks.** In Part 1, the participants did not take lacosamide or a placebo.

**Part 2 lasted 6 weeks.** The participants could enter Part 2 if they had 2 focal seizures during Part 1.

## In Part 2:

The participants started taking a placebo or a small amount of lacosamide. The study doctors slowly increased the amount until the participants were taking at least the lowest dose the researchers wanted to study.

**Part 3 lasted 10 weeks.** The participants could enter Part 3 if they reached at least the lowest dose of lacosamide the researchers wanted to study in Part 2.

## In Part 3:

The participants took a steady dose of a placebo or lacosamide.

After Part 3, some of the participants joined another study and the rest did not. The participants could choose to join the other study if they had completed Part 3.

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Before participants joined the other study, they kept taking the study treatment and their usual 1 to 3 anti-seizure medicines for 4 more weeks. During those 4 weeks:

- If they had taken lacosamide during Part 3, they kept taking it.
- If they had taken a placebo during Part 3, they began to take lacosamide and slowly took a higher dose.

The participants who did not join the other study took smaller and smaller amounts of lacosamide or a placebo for 2 to 4 weeks until they were not taking any. The participants also took their usual 1 to 3 anti-seizure medicines. They had a clinic visit 2 weeks after they stopped taking lacosamide or a placebo. Then they left the study.

### 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.

#### **How many focal seizures did the participants have during the study?**

The researchers wanted to learn how many focal seizures the participants had when they took lacosamide with their 1 to 3 usual anti-seizure medicines. They compared this to how many focal seizures the participants had when they took placebo with their usual 1 to 3 anti-seizure medicines.

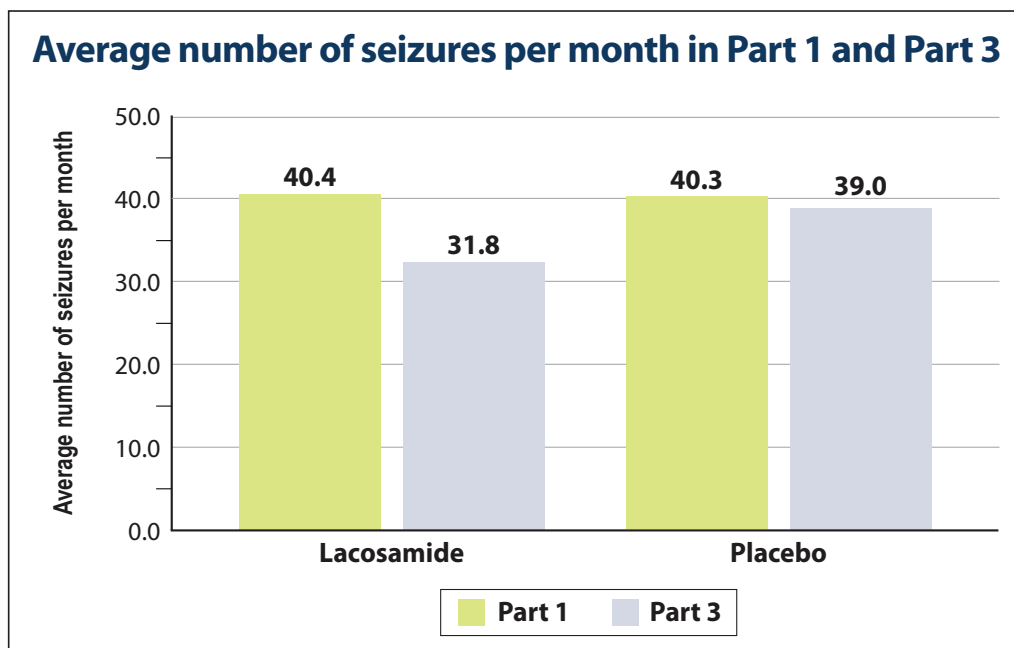
The researchers measured the number of focal seizures participants had in Part 1 and the number of focal seizures they had in Part 3. They compared the change in the number of seizures from Part 1 to Part 3.

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The researchers found that there was a decrease in focal seizures in both treatment groups from Part 1 to Part 3. This decrease was larger in the participants who took lacosamide compared with the participants who took a placebo. The researchers used a mathematical method called “analysis of covariance” to determine these numbers.

- The participants who took lacosamide had an average of 40.4 focal seizures per month during Part 1 compared with an average of 31.8 focal seizures per month during Part 3.
- The participants who took a placebo had an average of 40.3 focal seizures per month during Part 1 compared with an average of 39.0 focal seizures per month during Part 3.

The graph below shows these results.



## What medical problems did the participants have?

This section is a summary of the medical problems the participants had during the study that the study doctors thought might be related to the treatments. These medical problems are called “adverse reactions”. Some participants had more than 1 adverse reaction.

An adverse reaction is considered “serious” when it puts the participant’s life at risk, requires hospitalization, causes disability, causes a baby being born with medical problems, or may have turned into one of these problems if not treated.

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These adverse reactions may or may not be caused by the treatments in the study. The results from several studies are needed to decide if a treatment causes an adverse reaction.

### How many participants had serious adverse reactions?

There were 0.3% of participants who had a serious adverse reaction. This was 1 of the 343 participants. The serious adverse reaction was vomiting. The participant who had this serious adverse reaction was taking lacosamide.

None of the participants taking a placebo had serious adverse reactions.

None of the participants died due to serious adverse reactions.

The table below shows these results:

Number of participants with serious adverse reactions during the study		
	Lacosamide (out of 171 participants)	Placebo (out of 172 participants)
How many participants had serious adverse reactions?	0.6% (1)	0.0% (0)
How many participants died due to serious adverse reactions?	0.0% (0)	0.0% (0)

### How many participants had any adverse reactions?

Overall, 29.2% of participants had adverse reactions that were either serious or not serious. This was 100 out of all 343 participants. More participants taking lacosamide had adverse reactions than participants taking a placebo.

Overall, 3.2% of the participants left the study due to adverse reactions. This was 11 out of all 343 participants. About the same number of participants in each treatment group left the study because of adverse reactions.

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The table below shows these results:

<b>Number of participants with adverse reactions during the study</b>		
	<b>Lacosamide (out of 171 participants)</b>	<b>Placebo (out of 172 participants)</b>
How many participants had adverse reactions?	33.9% (58)	24.4% (42)
How many participants left the study due to adverse reactions?	2.9% (5)	3.5% (6)

### **What adverse reactions did the participants have?**

The most common adverse reactions during this study were dizziness and sleepiness. These both happened in more participants taking lacosamide than a placebo.

The table below shows the adverse reactions that happened in 5% or more of the participants in either treatment group. This means they happened in at least 1 out of every 20 participants in either treatment group. There were other adverse reactions, but these all happened in fewer participants.

<b>Adverse reactions in 5% or more of the participants in either treatment group</b>		
	<b>Lacosamide (out of 171 participants)</b>	<b>Placebo (out of 172 participants)</b>
Dizziness	8.8% (15)	5.8% (10)
<u>Sleepiness</u>	14.0% (24)	5.8% (10)



### How has this study helped patients and researchers?

The results of this study have helped researchers learn more about using lacosamide in children and teenagers 4 years of age and older with epilepsy. The results of this study might be used in other studies to compare lacosamide with other treatments for people who have a similar condition.

Deciding which treatments work best for patients almost always takes results from several studies. This summary shows only the main results from this 1 study. Other studies may provide new information or different results.

This summary is provided for informational purposes only. If you need medical advice about your or your child's health or situation, please contact your doctor.

When this study ended, further clinical studies with lacosamide were planned.

### Where can I learn more about this study?

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

- <https://clinicaltrials.gov/ct2/show/NCT01921205?term=NCT01921205&rank=1>
- <https://www.clinicaltrialsregister.eu/ctr-search/trial/2012-004996-38/results>

If you have questions about this study, you can contact UCB by email at [datasharing@ucb.com](mailto:datasharing@ucb.com).

## Study Information

**Protocol number:** SP0969

**Study Sponsor:** UCB BIOSCIENCES Inc. sponsored this study. It is now called UCB Biopharma SPRL and is referred to as UCB in this summary.

**Treatment studied:** lacosamide

**Short Study Title:** This study was done to see if lacosamide worked and to learn about its safety in children and teenagers 4 years of age and older with epilepsy.

**Full Study Title:** A multicenter, double-blind, randomized, placebo-controlled, parallel-group study to investigate the efficacy and safety of lacosamide as adjunctive therapy in subjects with epilepsy  $\geq 4$  years to  $< 17$  years of age with partial-onset seizures

**National Clinical Study number:** NCT01921205

**EudraCT number:** 2012-004996-38

## Glossary

Sleepiness:	Also called “somnolence.”
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