

Clinical Study Results



Study Sponsor: UCB Biopharma SRL

Treatment Studied: Lacosamide

Protocol Number: EP0008

Short Study Title: A study to learn if lacosamide helps control seizures in Chinese and Japanese participants with epilepsy who are taking their usual anti-seizure medicines

Thank you!

The sponsor of this study, UCB, thanks all the participants of this study. All the participants helped the researchers learn more about using lacosamide in people with epilepsy.

This is a summary of the main results of this study. An independent, non-profit organization called CISCRP helped prepare this summary of the study results.

We think it is important to share the results with the participants and the public. We hope this summary helps the participants understand and feel proud of 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 your study doctor or the study staff.

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 if lacosamide worked in a large number of Chinese and Japanese participants with epilepsy. They also wanted to learn if these 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 1 part of the brain. These are called focal seizures, also called partial onset seizures. The term focal seizures is used throughout this summary. The participants in this study had focal seizures.

Lacosamide helps to reduce uncontrolled electrical activity in the brain that causes seizures. When this study started, lacosamide was not available in China and Japan as a treatment for people with epilepsy.

What were the main questions studied?

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

- Did the participants who took lacosamide have fewer seizures?
- What medical problems did the participants have during the study?

Who participated in the study?

There were 547 male and female participants in China and Japan who joined the study and took at least 1 dose of study treatment. They were 16 to 67 years old.

The researchers planned to include Chinese and Japanese participants with epilepsy who:

- Had focal seizures for more than 2 years before they joined the study, even after taking 2 or more anti-seizure medicines
- Had at least 4 focal seizures in the 28 days before they joined the study
- Were taking steady doses of 1 to 3 anti-seizure medicines for at least the 4 weeks right before they joined the study
- Had never taken lacosamide in a study before
- Weighed at least 40 kilograms

Each participant was in the study for up to 28 weeks, but the whole study lasted for about 2 years. The study started in September 2012 and ended in August 2014.



What treatments did the participants take?

During this study, the participants took either lacosamide pills or placebo pills twice each day for up to 18 weeks. The placebo pills looked like lacosamide pills, but did not have any lacosamide in them. The researchers used the placebo to help make sure the effects of lacosamide they found in the study were actually caused by it. The doses of lacosamide were measured in milligrams, also called mg.

During the study, there were 3 treatment groups:

-  184 participants were in the group that took the placebo each day.
-  183 participants were in the group that took 200 mg of lacosamide each day.
-  180 participants were in the group that took 400 mg of lacosamide each day.

None of the participants, study doctors, or other study staff knew what treatment each participant was taking. UCB also did not know. This was done 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.

The participants took their usual 1 to 3 anti-seizure medicines during the study.

What happened during the study?

This section shows how the study was planned to be done.

Before joining the study, all the participants first learned about the study and then decided they wanted to join. This is called “informed consent.” After this, the study doctors and study staff asked the participants about their medical history and checked their health to make sure they could join the study. This part lasted up to 1 week.

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During the study:

-  The participants or their caregivers kept track of their seizures every day using diaries.
-  The participants visited the clinic up to 9 times.
-  The study doctors kept track of any medical problems reported by the participants or observed by the doctors or study staff.
-  The participants gave blood and urine samples at some clinic visits.
-  The participants kept taking their usual 1 to 3 anti-seizure medicines during the entire study.

The study had 3 main parts.

Part 1 lasted 8 weeks. During Part 1, the participants took steady doses of their usual 1 to 3 anti-seizure medicines. They did not take any study treatments.

Part 2 lasted 4 weeks. During Part 2, the participants took either the placebo or lacosamide. For the participants who took lacosamide, the doses were slowly increased until they reached either:

-  200 mg of lacosamide each day
-  400 mg of lacosamide each day

At the end of Part 2, the study doctors could choose to lower a participant's lacosamide dose.

- In the 200 mg lacosamide group, the study doctors could lower the dose to 100 mg each day.
- In the 400 mg lacosamide group, the study doctors could lower the dose to 300 mg each day.

The participants who completed Part 2 could join Part 3. The participants who did not reach the end of Part 2 left the study.



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Part 3 lasted 12 weeks. During this part, the participants continued taking study treatments as they had at the end of Part 2. The participants who could not tolerate the study treatment during Part 3 left the study.

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

The participants who joined the other study stayed in this study for up to 2 more weeks. During this time, their lacosamide dose was adjusted to 200 mg each day.

The participants who did not join the other study took the placebo or lower doses of lacosamide for 1 week until they were not taking any. They had a clinic visit 2 weeks after they stopped taking study treatment. 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.

In the results below, the researchers included only the participants who stayed in the study after Part 1. They did not include participants who had important changes from the study plan that might have affected the conclusions about the study results. The researchers decided what type of changes might affect their conclusions before they looked at the study results.

The results shown below include 544 of the 547 participants:

- 183 participants were in the placebo group.
- 182 participants were in the 200 mg lacosamide group.
- 179 participants were in 400 mg lacosamide group.

For the results shown below:

- The participants who had their dose lowered to 100 mg of lacosamide each day are included in the 200 mg lacosamide group.
- The participants who had their dose lowered to 300 mg of lacosamide each day are included in the 400 mg lacosamide group.



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Did the participants who took lacosamide have fewer seizures?

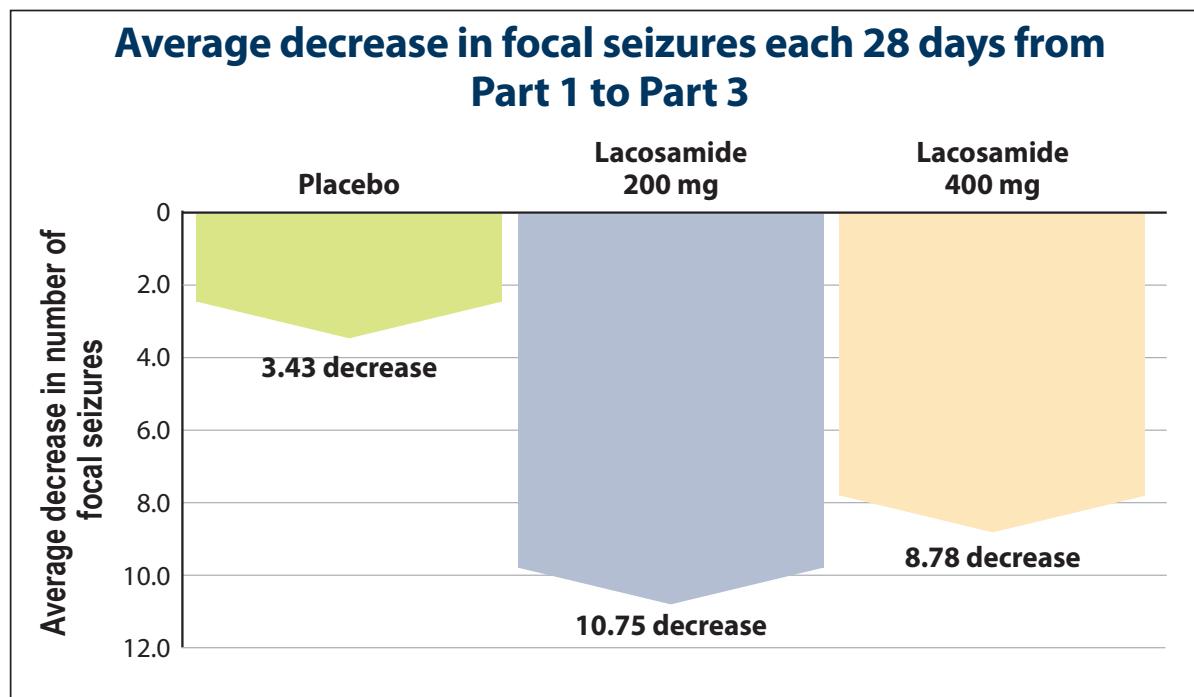
Yes. In this study, the participants who took lacosamide had bigger decreases in the number of focal seizures compared with those who took the placebo.

To find this answer, the researchers compared the number of focal seizures the participants recorded in their diaries in Part 1 and Part 3. They looked at the number of seizures during every 28 days.

The researchers found that the average number of focal seizures each 28 days decreased in each treatment group. They found that the average decreases were bigger in the lacosamide groups than in the placebo group. There was an average decrease of:

- 3.43 seizures each 28 days in the placebo group
- 10.75 seizures each 28 days in the 200 mg lacosamide group
- 8.78 seizures each 28 days in the 400 mg lacosamide group

The chart below shows these results. The participants took their usual 1 to 3 anti-seizure medicines while they were taking study treatments.



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 1 of these problems if not treated.

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.

The information below includes all 547 participants who got the placebo or lacosamide at least 1 time. Part 1 is not included because none of the participants were taking study treatments during this part.

How many participants had serious adverse reactions?

During Part 2 and Part 3 of this study, serious adverse reactions happened in:

- 0.5% of the participants in the placebo group. This was 1 out of 184 participants.
- 0.5% of the participants in the 200 mg lacosamide group. This was 1 out of 183 participants.
- 1.1% of the participants in the 400 mg lacosamide group. This was 2 out of 180 participants.

None of the participants died due to serious adverse reactions.

What serious adverse reactions did the participants have?

The list below shows the serious adverse reactions that happened during Part 2 and Part 3 of this study.

- 1 participant in the placebo group had seizures that last too long or that happen back to back.
- 1 participant in the 200 mg lacosamide group had a suicide attempt.
- 1 participant in the 400 mg lacosamide group had dizziness.
- 1 participant in the 400 mg lacosamide group had heavy bleeding in the upper part of the gastrointestinal tract, injury to the liver due to a drug, and a lung infection.

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How many participants had any adverse reactions?

During Part 2 and Part 3 of the study, adverse reactions happened in:

- 25.5% of the participants in the placebo group. This was 47 out of 184 participants.
- 35.0% of the participants in the 200 mg lacosamide group. This was 64 out of 183 participants.
- 60.6% of the participants in the 400 mg lacosamide group. This was 109 out of 180 participants.

What adverse reactions did the participants have?

The most common adverse reaction in each of the treatment groups during Part 2 and Part 3 of the study was dizziness.

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

Adverse reactions in 5% or more of participants in any treatment group during Parts 2 and 3

	Placebo (out of 184 participants)	Lacosamide 200 mg (out of 183 participants)	Lacosamide 400 mg (out of 180 participants)
Dizziness	8.2% (15)	13.7% (25)	32.2% (58)
Sleepiness	2.2% (4)	7.7% (14)	10.0% (18)
Vomiting	1.6% (3)	1.6% (3)	6.7% (12)
Double vision	0.5% (1)	2.2% (4)	6.7% (12)



How has this study helped patients and researchers?

The results of this study have helped researchers learn more about using lacosamide in people with epilepsy. The results of this study may be used in other studies to compare lacosamide with other treatments for people who have a similar condition.

The results of this study are based only on the participants included in the study.

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.

This 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 study 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 website listed below:

- <https://clinicaltrials.gov/ct2/show/NCT01710657?term=NCT01710657&rank=1>

If you have questions about this study, you can contact UCB by email at datasharing@ucb.com.



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Study Information

Protocol Number: EP0008

Study Sponsor: UCB Biopharma SRL sponsored this study. In this summary, UCB Biopharma SRL is referred to as UCB. In the protocol, the sponsor is referred to as UCB Japan Co. Ltd and UCB Pharma SA.

Full Study Title: A multicenter, double-blind, randomized, placebo-controlled, parallel-group study to evaluate the efficacy and safety of lacosamide as adjunctive therapy in Japanese and Chinese adults with uncontrolled partial-onset seizures with or without secondary generalization

National Clinical Study Number: NCT01710657

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.

Glossary

Description	Also called
Double vision	Diplopia
Heavy bleeding in the upper part of the gastrointestinal tract	The gastrointestinal tract is a tube that carries food through the body. Heavy bleeding along the upper part of the tube is called upper gastrointestinal haemorrhage.
Injury to the liver due to a drug	Drug-induced liver injury
Lung infection	Pneumonia
Seizures that last too long or that happen back to back	Status epilepticus
Sleepiness	Somnolence



This summary was last updated on 20 February 2020.
The final clinical study report is dated 21 February 2016.