Clinical Study Results

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Study Sponsor: UCB BIOSCIENCES Inc.

Treatment Studied: Lacosamide

Protocol Number: SP0982

Short Study Title: A study to learn if lacosamide reduced generalized tonic-clonic seizures in children and adults 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 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, their caregivers, and the public. We hope this summary helps the participants and their caregivers understand and feel proud of their important role in medical research.

The purpose of this summary is only to share information. If you or the child you care for needs medical advice, please contact your or your child's doctor. If you or the child in your care participated in this study and have questions about the results, please speak with a study doctor or 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 participants with epilepsy. They also wanted to learn if the participants had any medical problems during the study.

Epilepsy is a brain disorder that causes seizures. Seizures can be different for each person but often include uncontrollable shaking of some parts of the body or the whole body and loss of consciousness. Epileptic seizures that cannot be controlled by epilepsy medications are also known as refractory seizures or uncontrolled seizures.

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The type of seizure that can cause someone to lose consciousness and shake violently is called a generalized tonic-clonic seizure. This is also known as a GTC seizure. Researchers think that taking lacosamide may help reduce GTC seizures.

In this study, the researchers wanted to find out if lacosamide helped reduce GTC seizures in children and adults with epilepsy.

What were the main questions studied?

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

- Did lacosamide affect how many participants had at least 2 GTC seizures during the study?
- What medical problems did the study doctors think might be related to the study treatments?

Who participated in the study?

There were 242 male and female participants who joined this study and took study treatment. They were 4 to 66 years old. This included:

- 55 children who were under 18 years old
- 187 adults who were over 18 years old

The study included participants who took study treatment in 22 countries: Australia, Belgium, Brazil, Bulgaria, China, the Czech Republic, France, Germany, Hungary, Israel, Italy, Japan, Mexico, Poland, Portugal, Romania, Russia, Slovakia, Spain, South Korea, Taiwan, and the United States.

In this study, the researchers planned to include participants with epilepsy who:

- Were already taking up to 3 epilepsy medications but were still having uncontrolled GTC seizures
- Had at least 3 GTC seizures within the 16 weeks before starting the study

Each participant was in the study for up to about 8 months, but the entire study lasted for about 4 years. The study started in April 2015 and ended in June 2019.

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What treatments did the participants take?

The participants in this study took lacosamide or a placebo in addition to their regular epilepsy medication. The adults took their study treatments as tablets by mouth, and the children took their study treatments as a syrup.

The placebo looked like lacosamide but did not have any lacosamide or any other drugs in it. The researchers used the placebo to help make sure the effects of lacosamide they found in the study were actually caused by lacosamide.

None of the participants or their caregivers, study doctors, or study staff knew what treatment each participant was taking. UCB staff 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.

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 for the treatments was as accurate as possible.

There were:

- 121 participants who took lacosamide
- 121 participants who took the placebo

The participants took study treatment for up to 28 weeks.

During the first 6 weeks, the participants slowly increased their dose of lacosamide until they were taking their full dose. The full dose of lacosamide for each participant depended on their age and weight. This could be up to 400 milligrams, also known as mg, per day.

During the next 18 weeks, the participants continued taking their full dose depending on their age and weight.

During the next 4 weeks, the participants either slowly decreased their dose of lacosamide or the placebo until they were taking none, or they could choose to continue taking their study treatment by joining another study for lacosamide.

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The chart below shows the treatments the researchers studied.

	121 participants took lacosamide
	121 participants took the placebo
	The participants took lacosamide or the placebo as tablets or as a syrup by mouth
	The participants took their dose of lacosamide or the placebo twice a day for up to 28 weeks

What happened during this study?

Before joining the study, the participants visited their clinic 1 time and had 1 telephone call. Each participant or their parent or caregiver learned about the study and decided to join the study. This is called “informed consent”. Then, the study doctors and study staff asked about the participants’ medical history and checked their health to make sure they could join the study. This part lasted up to 4 weeks.

The study doctors:

	Kept track of any medical problems reported by the participants or observed by the study doctors or study staff
	Took blood and urine samples
	If needed, checked the participants’ heart health using an electrocardiogram, also known as an ECG
	If needed, checked the participants’ brain health using an electroencephalogram, also known as an EEG

The study doctors also did these tests and measurements at other visits during the study.

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During the study, the participants visited their clinic 9 times and had 3 telephone calls for over up to 28 weeks. They took lacosamide or the placebo at home twice a day in addition to their regular epilepsy medication. They also kept a diary of their seizures and answered questionnaires about their symptoms and quality of life.

If any participant had more than 2 seizures after at least 6 weeks in the study, they left the study. They continued taking their regular epilepsy medication under their doctors' advice.

At the end of the study, the participants could join a new study for lacosamide. These participants visited their clinic for this study 1 last time. The participants who did not join the new study visited their clinic for this study 1 time and had 1 telephone call. At these visits, the study doctors checked the participants' health and asked about any medical problems they were having.

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.

The results below include 240 out of 242 participants. This is because some participants left the study before getting all of the treatments.

Did lacosamide affect how many participants had at least 2 GTC seizures during the study?

Yes. Overall, the study showed that lacosamide reduced the number of participants who had at least 2 GTC seizures during the study.

To answer this question, the researchers kept track of all of the GTC seizures that the participants had during the study. They counted how many participants had at least 2 of these seizures and left the study. They stopped counting once 125 participants had at least 2 GTC seizures.

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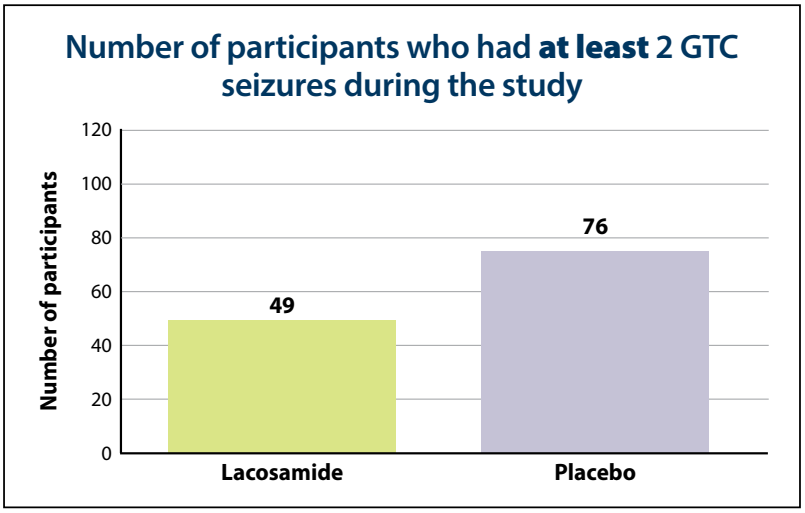
Out of these 125 participants who had at least 2 GTC seizures, the researchers found that:

- 49 participants took lacosamide
- 76 participants took the placebo

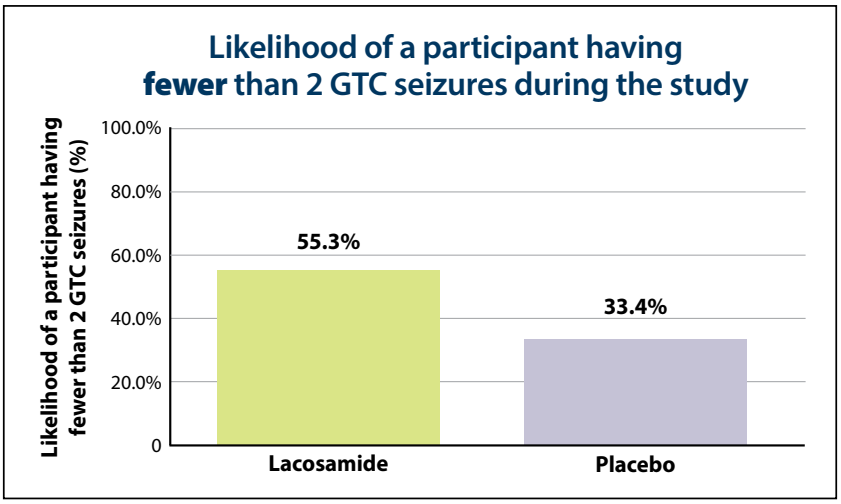
These results are shown in the chart below.



Based on these results, the researchers also calculated how likely it would be for a participant to have fewer than 2 GTC seizures. They calculated this as a percentage. The researchers found that the likelihood of a participant having fewer than 2 GTC seizures during the study was:

- 55.3% for the participants who took lacosamide
- 33.4% for the participants who took the placebo

These results are shown in the chart below.



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What medical problems did the study doctors think might be related to the study treatments?

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 study treatments. In this summary, 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 related to the study treatments. The results from several studies are often needed to decide what medical problems are actually caused by a treatment. Always talk to a doctor before making any treatment decisions.

How many participants had serious adverse reactions?

Serious adverse reactions happened in:

- 3.3% of participants who took lacosamide. This was 4 out of 121 participants.
- 0.8% of participants who took the placebo. This was 1 out of 121 participants.

None of the participants died because of serious adverse reactions.

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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. The most common serious adverse reaction was sleepiness.

Serious adverse reactions during the study

Serious adverse reaction	**Lacosamide** (out of 121 participants)	**Placebo** (out of 121 participants)
Sleepiness	1.7% (2)	0.0% (0)
Dizziness	0.8% (1)	0.0% (0)
Increase of proteins called transaminases	0.8% (1)	0.0% (0)
Nausea	0.8% (1)	0.0% (0)
Seizures that last too long or happen back to back	0.8% (1)	0.0% (0)
Vomiting	0.8% (1)	0.0% (0)
Broken leg	0.0% (0)	0.8% (1)

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How many participants had any serious or non-serious adverse reactions?

Adverse reactions happened in:

- 46.3% of participants who took lacosamide. This was 56 out of 121 participants.
- 34.7% of participants who took the placebo. This was 42 out of 121 participants.

What serious or non-serious adverse reactions did the participants have?

The table below shows the serious or non-serious adverse reactions that happened in 5.0% or more participants in either of the treatment groups. This means they happened in at least 6 out of every 120 participants in either of the treatment groups. There were other adverse reactions, but these happened in fewer participants.

Adverse reactions in 5.0% or more of participants in either treatment group

Adverse reaction	Lacosamide (out of 121 participants)	Placebo (out of 121 participants)
Dizziness	17.4% (21)	3.3% (4)
Sleepiness	13.2% (16)	11.6% (14)
Nausea	7.4% (9)	2.5% (3)
Feeling of spinning	5.8% (7)	1.7% (2)
Vomiting	5.0% (6)	0.0% (0)
Tiredness	5.0% (6)	2.5% (3)

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How has this study helped patients and researchers?

The results of this study have helped researchers learn more about using lacosamide in participants with epilepsy.

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.

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.

The results of this study may be used in other studies to compare lacosamide with other treatments for people who have epilepsy.

At the time this study ended, further clinical studies in GTC epilepsy with lacosamide were not planned.

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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/NCT02408523
- www.clinicaltrialsregister.eu/ctr-search/search?query=2011-003100-21

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

Study Information

Protocol Number: SP0982

Study Sponsor: UCB BIOSCIENCES, Inc. sponsored this study. It is referred to as UCB in this summary.

Full Study Title: A double-blind, randomized, placebo-controlled, parallel-group, multicenter study to evaluate the efficacy and safety of lacosamide as adjunctive therapy for uncontrolled primary generalized tonic-clonic seizures in subjects with idiopathic generalized epilepsy

National Clinical Study Number: NCT02408523

EudraCT Number: 2011-003100-21

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.

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Glossary

Description	Also called
Broken leg	Fractured femur
Feeling of spinning	Vertigo
Increase of a protein called transaminase	Transaminases are proteins made by the liver and other parts of the body. An increase in these proteins is also called “transaminases increased”.
Seizures that last too long or happen back to back	Status epilepticus
Sleepiness	Somnolence
Tiredness	Fatigue

This summary was last updated on 11 May 2021.
The final clinical study report is dated 05 September 2019.

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