

Clinical Study Results

This is a summary of the main results of a clinical study for the drug lacosamide. This study is sometimes called the ALEX-MT study.

UCB Biopharma SPRL sponsored this study and wants to share the results with the participants 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 people 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 need medical advice, please contact your doctor. If you 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 well lacosamide worked in a large number of participants with epilepsy.

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. It was approved for use with other anti-seizure medicines, not by itself. The researchers in this study wanted to find out how lacosamide worked when taken by itself.

What were the main questions studied?

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

- How many participants left the study due to seizures getting worse?
- What medical problems did the participants have during the study?

Who participated in the study?

Males and females diagnosed with epilepsy who had focal seizures participated in this study. The participants in the study were 16 to 69 years old.

All the participants in the study:

- Were taking 1 or 2 other anti-seizure medicines for at least 28 days before they started taking lacosamide in this study
- Had at least 2 but not more than 40 focal seizures over 28 days during the 8 weeks before they started taking lacosamide in this study
- Had not taken lacosamide pills before, but may have had 1 injected dose of lacosamide

The study included 425 participants in 9 countries: Australia, Canada, Denmark, Germany, Italy, Poland, Spain, United Kingdom, and United States.

Each participant was in the study for up to 30 weeks, but the entire study lasted for a little more than 5 years. The study started in August 2007 and ended in December 2012.

What treatments did the participants take?







All of the participants in this study took lacosamide. Participants took 2 different doses of lacosamide so researchers could compare the results with previous studies.

This was a “double-blind” study. This means none of the participants, doctors, or other study staff knew the dose of lacosamide each participant was taking. UCB also did not know the doses.

Some studies are done this way because knowing what dose of the treatment the participants are taking can affect the results of the study. When UCB reviewed the results of the study, they learned the dose of lacosamide each participant took so they could create a report of the results.

The researchers used a computer program to randomly choose which dose each participant took. This helped make sure the doses were chosen fairly and the results for the treatments were compared as accurately as possible.

The chart below shows the treatments the participants took during the study:

 106 participants in this study got 300 milligrams of lacosamide a day.	 319 participants in this study got 400 milligrams of lacosamide a day.
 The participants took lacosamide pills 2 times a day during the study.	 The participants took lacosamide pills 2 times a day during the study.
 Each pill of lacosamide had 50 or 100 milligrams of lacosamide.	 Each pill of lacosamide had 50 or 100 milligrams of lacosamide.

What happened during the study?

Before the study started, all the participants decided to take part after learning about the study. This is called “informed consent.” Then the doctors and nurses asked the participants about their medical history and checked their health to make sure they could join the study.

During the study:



The participants kept track of their seizures every day using diaries.



The participants gave blood and urine samples at some clinic visits. They also got electrocardiograms, which are tests that record the electrical activity of the heart.



The researchers kept track of the medical problems reported by the participants and observed by the doctors.

There were 3 main parts of the study:

Part 1 lasted 8 weeks.

In Part 1, the participants kept taking their usual anti-seizure medicines.

Part 2 lasted 3 weeks.



In Part 2, participants started taking lacosamide. The dose of lacosamide was slowly increased until the full dose the researchers wanted to study was reached.

Part 3 lasted 16 weeks.



In Part 3, the participants stopped taking their other anti-seizure medicines. They kept taking lacosamide. They took the same dose of lacosamide throughout Part 3.

After Part 3, some participants entered another study and the rest did not. Participants could choose to enter another study only if they had completed Part 3. Not all of the participants entered the other study.

- The participants who entered the other study kept taking lacosamide. The participants, doctors, and other study staff in the other study knew how much lacosamide the participants were taking.
- The participants who did not enter the other study started taking their other anti-seizure medicines. They took a smaller amount of lacosamide for 1 week. They had a clinic visit 2 weeks after they stopped taking lacosamide. Then they left this 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 participants left the study due to seizures getting worse?

The researchers measured the number of participants who left the study while taking 400 milligrams of lacosamide and no other anti-seizure medicines in Part 3.

The researchers also measured the number of participants who left the study while taking 300 milligrams of lacosamide and no other anti-seizure medicines in Part 3, but this was not the main question this study was designed to answer. So, the results below are only for participants taking 400 milligrams of lacosamide.

The researchers found:

- 30.0% of the participants taking 400 milligrams of lacosamide left the study because their focal seizures got worse

A mathematical method called a “Kaplan-Meier estimate” was used to determine this number. Since participants left Part 3 at different times, the method used information collected in Part 3 until the time that each participant left.

The participants left the study if they met the “exit requirements.” These exit requirements included:

- If participants had more seizures
- If the seizures they had were more severe
- If the seizures happened more often
- If the seizures lasted longer

The researchers also compared the number of participants who left the study to the number who left previous similar studies. The percentage of participants who left this study because their seizures got worse was lower than the previous studies.

What medical problems did the participants have?

This section is a summary of the medical problems the participants had during the study that the doctors thought might be related to the treatments. These medical problems are called “adverse reactions.” Some participants had more than 1 adverse reaction. Seizures were only counted as adverse reactions if they got worse or improved.

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.

Adverse reactions are shown below for both the 300 milligram dose and 400 milligram dose of lacosamide. The study was not designed to make comparisons between the doses.

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 1.9% of participants who had serious adverse reactions during the study. This was 8 out of all 425 participants.

None of the participants died due to serious adverse reactions.

The table below shows these results:

Number of participants with serious adverse reactions		
	Lacosamide 300 milligrams each day (out of 106 participants)	Lacosamide 400 milligrams each day (out of 319 participants)
How many participants had serious adverse reactions?	1% (1)	2.2% (7)
How many participants died due to serious adverse reactions?	0% (0)	0% (0)

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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. More participants had seizures than any other serious adverse reaction.

Serious adverse reactions		
	Lacosamide 300 milligrams each day (out of 106 participants)	Lacosamide 400 milligrams each day (out of 319 participants)
<u>Seizure</u>	0.9% (1)	1% (3)
Abnormal behavior	0.0% (0)	0.3% (1)
Epilepsy	0.0% (0)	0.3% (1)
Headache	0.0% (0)	0.3% (1)
<u>Rash due to drug</u>	0.0% (0)	0.3% (1)
<u>Unusual amounts of a hormone called “antidiuretic hormone”</u>	0.0% (0)	0.3% (1)

How many participants had any adverse reactions?

Overall, 58.8% of participants had adverse reactions that were either serious or not serious during Parts 2 and 3 of the study. This was 250 out of all 425 participants. Fewer participants had adverse reactions after Part 3.

Overall, 9.6% of the participants left Parts 2 and 3 due to adverse reactions. This was 41 out of all 425 participants. One participant left after Part 3 due to an adverse reaction.

The table below shows these results.

Number of participants with adverse reactions during Parts 2 and 3		
	Lacosamide 300 milligrams each day (out of 106 participants)	Lacosamide 400 milligrams each day (out of 319 participants)
How many participants had adverse reactions?	57.5% (61)	59.2% (189)
How many participants left the study due to adverse reactions?	6.6% (7)	10.7% (34)

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What adverse reactions did the participants have?

The table below shows the adverse reactions that happened in 5% or more participants in either treatment group during Parts 2 and 3 of the study. This means they happened in at least 1 out of every 20 participants in either group. There were other adverse reactions during this study, but these happened in fewer participants.

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

	Lacosamide 300 milligrams each day (out of 106 participants)	Lacosamide 400 milligrams each day (out of 319 participants)
Dizziness	16.0% (17)	21.0% (67)
<u>Sleepiness</u>	14.2% (15)	7.5% (24)
<u>Tiredness</u>	8.5% (9)	8.8% (28)
Headache	9.4% (10)	8.2% (26)
Nausea	5.7% (6)	9.1% (29)
<u>Seizure</u>	6.6% (7)	6.0% (19)
<u>Shaking of the body</u>	6.6% (7)	5.3% (17)

How has this study helped patients and researchers?

The results of this study have helped researchers learn more about using lacosamide by itself in people who have epilepsy with focal seizures. The results might 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 on the participants included in this 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 summary is provided for informational purposes only. If you need medical advice about your own health or situation, please contact your physician.

Further clinical studies with lacosamide are 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/NCT00520741?term=ALEX-MT&rank=1> “NCT00520741” or “ALEX-MT” identifies this study on clinicaltrials.gov, not the protocol number “SP902”.

<https://www.clinicaltrialsregister.eu/ctr-search/trial/2007-005439-27/results>

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

Study Information

Protocol Number: SP902

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 when used by itself and to get information about its safety in participants with epilepsy who have focal seizures.

Full Study Title: A historical-controlled, multicentre, double blind, randomized trial to assess the efficacy and safety of conversion to lacosamide 400mg/day monotherapy in subjects with partial onset seizures.

National Clinical Study Number: NCT00520741

EudraCT Number: 2007-005439-27

Glossary

ALEX-MT:	A short name for this study. The short name stands for “A Lacosamide Exchange to Monotherapy Trial.”
Rash due to drug:	It is a certain kind of rash that looks like it is caused by a drug. Also called a “drug eruption.”
Seizure:	Also called “convulsion.”
Shaking of the body:	Shaking of the body that the person can’t control. Also called “tremor.”
Sleepiness:	Also called “somnolence.”
Tiredness:	Also called “fatigue.”
Unusual amounts of a hormone called antidiuretic hormone:	This is when the body makes the wrong amount of antidiuretic hormone. Antidiuretic hormone is the molecule that helps a person keep the right balance of fluids in their body. Also called “inappropriate antidiuretic hormone secretion.”

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