# Clinical Study Results

Inspired by patients. Driven by science.

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 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 recently diagnosed 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. Sometimes focal seizures can spread to the whole brain. There are other types of seizures that seem to start in both sides of the brain at once. The most severe type of these seizures is called a grand mal seizure. The participants in this study had focal seizures or grand mal 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.



Protocol number: SP0993

The researchers in this study wanted to find out how lacosamide worked when taken by itself. They compared lacosamide to an anti-seizure medicine called carbamazepine. At the time of this study, carbamazepine was often the first choice of doctors as a medicine to treat seizures and was approved to be used by itself.

## What were the main questions studied?

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

- How many participants did not have seizures for 6 months in a row?
- What medical problems did the participants have during the study?

## Who participated in the study?

Males and females with newly diagnosed epilepsy participated in this study. They were 16 to 87 years old.

All the participants in the study:

- Had at least 2 focal seizures or grand mal seizures in the 12 months before starting the study
- Had never taken lacosamide or carbamazepine before

The study included 886 participants in 29 countries: Australia, Belgium, Bulgaria, Canada, Czech Republic, Finland, France, Germany, Greece, Hungary, Italy, Japan, Latvia, Lithuania, Mexico, Philippines, Poland, Portugal, Romania, Russian Federation, Slovakia, South Korea, Spain, Sweden, Switzerland, Thailand, Ukraine, United Kingdom, and United States.

Each participant was in the study for up to a little more than 2 years, but the whole study lasted about 4 and a half years. The study started in April 2011 and ended in August 2015.

# What treatments did the participants take?

The participants in this study took lacosamide or carbamazepine. The lowest dose for each drug was the smallest amount that the researchers thought might control seizures. The dose of each drug could then be either doubled or tripled during the study to help control participants' seizures.

This was a "double-blind" study. This means none of the participants, doctors, or other 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. 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 the treatment each participant took. This helped make sure the treatments were chosen fairly and that comparing the results of the treatments was as accurate as possible.

The chart below shows the treatments the participants took:

| | |
|---|---|
| 444 participants took 200 to 600 milligrams of lacosamide each day. | 442 participants took 400 to 1200 milligrams of carbamazepine each day. |
| Participants took lacosamide twice each day for up to 118 weeks. | Participants took carbamazepine twice each day for up to 118 weeks. |
| Each pill of lacosamide had 50 or 100 milligrams of lacosamide. | Each pill of carbamazepine had 200 milligrams of carbamazepine. |

## 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.

**At the beginning of the study,** doctors slowly increased the dose of drug the participants took to reach either:

- 200 milligrams of lacosamide each day
- 400 milligrams of carbamazepine each day

**After this,** participants began the main part of the study, which lasted for 6 months.

**During the main part of the study,** if participants had a seizure, doctors slowly increased the dose of drug to reach either:

- 400 milligrams of lacosamide each day
- 800 milligrams of carbamazepine each day

If participants had another seizure, doctors slowly increased the dose of drug to reach either:

- 600 milligrams of lacosamide each day
- 1200 milligrams of carbamazepine each day

If participants had another seizure after they reached the highest doses the researchers wanted to study, the participants slowly stopped taking lacosamide or carbamazepine and then left 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.

**After the main part of the study,** some participants entered another study and the rest did not. Participants could choose to enter the other study only if they had completed the main part of this study.

- The participants who entered the other study went straight into that study.
- The participants who did not enter the other study started taking their other anti-seizure medicines. They took smaller and smaller amounts of lacosamide or carbamazepine until they were not taking any. They had a clinic visit 2 weeks after they stopped taking lacosamide or carbamazepine. 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.

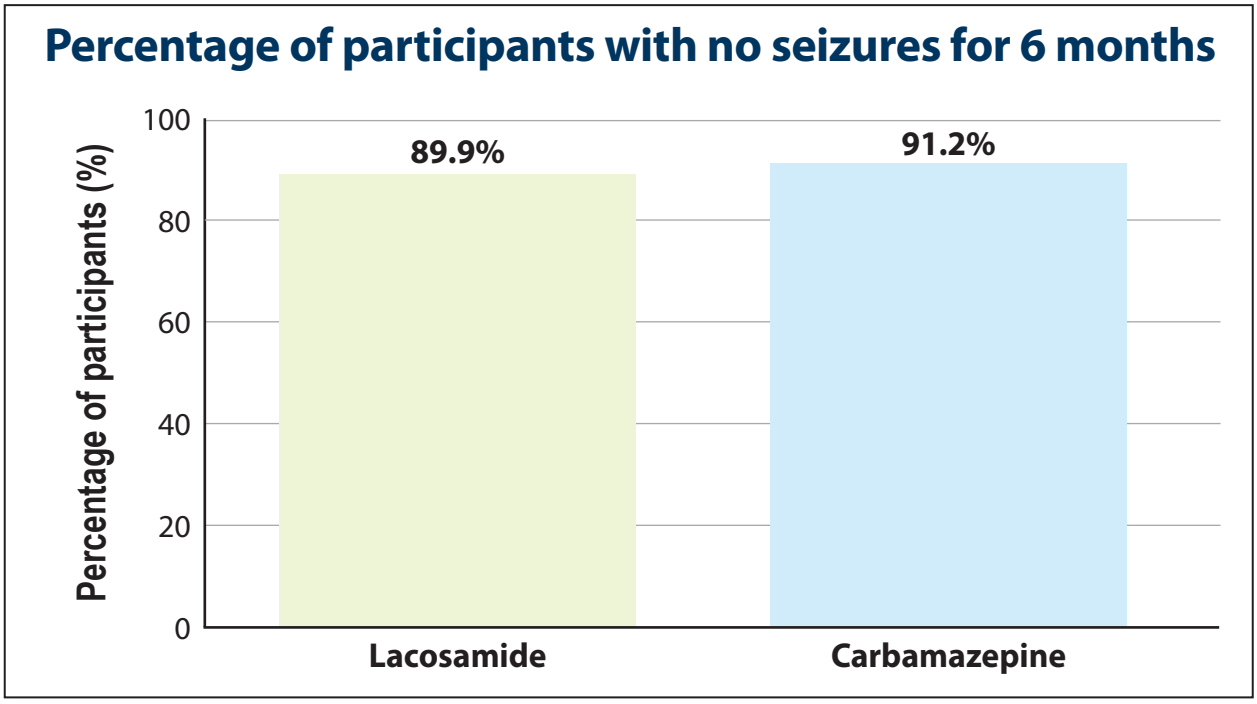
### How many participants did not have seizures for 6 months in a row?

The percentage of participants taking lacosamide who did not have seizures was about the same as the participants taking carbamazepine. The researchers found:

- 89.9% of participants taking lacosamide did not have seizures for 6 months in a row
- 91.2% of participants taking carbamazepine did not have seizures for 6 months in a row

A mathematical method called a "Kaplan-Meier estimate" was used to determine these numbers. For participants who completed the main part, the method used information from the entire 6 months. For participants who left the study before the main part ended, the method used information until the time they left.

The graph below shows the 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 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.

The adverse reactions shown in this summary 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?

Fewer participants taking lacosamide had serious adverse reactions compared with participants taking carbamazepine. There were 2.1% of participants who had serious adverse reactions during this study. This was 19 out of 886 participants.

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 444 participants) | Carbamazepine (out of 442 participants) |
|---|---|---|
| How many participants had serious adverse reactions? | 1.1% (5) | 3.2% (14) |
| How many participants died due to serious adverse reactions? | 0.0% (0) | 0.0% (0) |

## What serious adverse reactions did participants have?

There were 2 serious adverse reactions that happened in more than 1 participant. These were:

- Three participants who took carbamazepine had seizures that started on one side of the brain and spread to both sides.
- Two participants who took carbamazepine had a severe drug reaction called DRESS.

No one who took lacosamide had either of these serious adverse reactions.

All other serious adverse reactions happened in no more than 1 participant.

## How many participants had any adverse reactions?

Fewer participants taking lacosamide had adverse reactions than participants taking carbamazepine. Overall, 41.6% of participants had adverse reactions that were either serious or not serious. This was 369 out of 886 participants.

Fewer participants taking lacosamide left the study because of adverse reactions than participants taking carbamazepine. Overall, 11.2% of participants left the study due to adverse reactions. This was 99 out of 886 participants.

The table below shows these results:

| Number of participants with adverse reactions during the study | | |
|---|---|---|
| | **Lacosamide (out of 444 participants)** | **Carbamazepine (out of 442 participants)** |
| How many participants had adverse reactions? | 37.4% (166) | 45.9% (203) |
| How many participants left the study due to adverse reactions? | 8.1% (36) | 14.3% (63) |

## What adverse reactions did the participants have?

The table below shows the adverse reactions that happened in 5% or more of participants in either treatment group. 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 | | |
|---|---|---|
| | **Lacosamide (out of 444 participants)** | **Carbamazepine (out of 442 participants)** |
| Sleepiness | 4.5% (20) | 8.8% (39) |
| Dizziness | 7.9% (35) | 5.0% (22) |
| Tiredness | 5.6% (25) | 7.0% (31) |
| Headache | 4.1% (18) | 5.0% (22) |
| Increase of a protein called gamma glutamyltransferase | 0.9% (4) | 6.1% (27) |

## 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 newly diagnosed epilepsy with focal seizures or grand mal 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 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 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/NCT01243177
- https://www.clinicaltrialsregister.eu/ctr-search/search?query=2010-019765-28

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

# Study Information

**Protocol Number:** SP0993

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

**Treatments Studied:** lacosamide and carbamazepine

**Short Study Title:** This study was done to see if lacosamide worked by itself and to get information about its safety in people with newly diagnosed epilepsy who have focal seizures or grand mal seizures.

**Full Study Title:** A multicenter, double-blind, double-dummy, randomized, positive controlled study comparing the efficacy and safety of lacosamide (200 to 600mg/day) to controlled release carbamazepine (400 to 1200mg/day), used as monotherapy in subjects (≥16 years) newly or recently diagnosed with epilepsy and experiencing partial onset or generalized tonic clonic seizures

**National Clinical Study Number:** NCT01243177

**EudraCT Number:** 2010-019765-28

# Glossary

| | |
|---|---|
| Increase of a protein called gamma glutamyltransferase: | Gamma glutamyltransferase is made by the liver and other parts of the body. An increase is also called “gamma glutamyltransferase increased.” |
| Seizure that starts in one side of the brain and spreads: | Also called “partial seizures with secondary generalization.” |
| Severe drug reaction called DRESS: | DRESS stands for “drug reaction with eosinophilia and systemic symptoms.” It is a reaction to a drug that may include rash, fever, swollen lymph nodes, and an increase in blood cells called eosinophilia. It may also cause problems with some internal organs. |
| Sleepiness: | Also called “somnolence.” |
| Tiredness: | Also called “fatigue.” |

Last updated 08 Nov 2018.