

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 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.

People with epilepsy have seizures that happen again and again. Seizures are caused by uncontrolled electrical activity in the brain.

Lacosamide helps to reduce uncontrolled electrical activity in the brain that causes seizures. Before this study started, researchers studied the safety of lacosamide when it was given as a pill. Sometimes when people cannot take pills, they get their medicines through a needle into their vein. This is called intravenous infusion, also called IV infusion.

The researchers in this study wanted to learn about the safety of lacosamide when it was given to participants with focal seizures through an IV infusion.

What were the main questions studied?

The main question the researchers wanted to answer in this study was:

- What medical problems did the participants have during the study?

Who participated in the study?

The study included 9 participants in Japan. The participants in the study were Japanese men and women with epilepsy. They were 19 to 46 years old.

All the participants in the study:

- had seizures that start in just one part of the brain, also called focal seizures
- took lacosamide pills in another study right before they entered this study
- did not take lacosamide through an IV infusion before
- had no changes in their anti-seizure medications for 2 weeks before the study started




Each participant was in the study for up to a week, but the entire study lasted for about 6 months. The study started in June 2014 and ended in December 2014.

What treatments did the participants take?

All the participants in this study got lacosamide through an IV infusion. They did not take lacosamide as a pill during this study. But, they kept taking their other anti-seizure medicines. The participants were taking 1 to 3 other anti-seizure medicines.

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






	9 participants got lacosamide
	Lacosamide was given through an IV infusion <ul style="list-style-type: none">• The dose of lacosamide was 200 to 400 milligrams• The dose each participant got was the same as the dose in the pill they took in the earlier study
	<ul style="list-style-type: none">• Each participant got a lacosamide IV infusion in the morning and at night for up to 5 days• Each infusion took 30 minutes

This was an “open-label” study. This means the participants, study doctors, study staff and UCB knew what treatment the participants were taking.

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.” The study doctors and study staff then asked the participants about their medical history and checked their health to make sure they could join the study.

During the study:

	The participants got an IV infusion of lacosamide.
	The study doctors kept track of any medical problems reported by the participants or observed by the doctors or study staff.
	The participants kept track of their seizures using diaries.
	The participants gave blood and urine samples at some clinic visits.
	The participants had electrocardiograms, also called ECGs. These are tests that record the electrical activity in the heart.

The participants kept taking their other 1 to 3 anti-seizure medicines. When the study ended, the participants went back into the other study and took lacosamide as a pill again.

What were the results of the study?

This is a summary of the main results from this study. These results are 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.

What medical problems did the participants have during the study?

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 of the 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.

These adverse reactions may or may not be caused by the treatment 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?

None of the participants had serious adverse reactions.

How many participants had any adverse reactions?

There were 22.2% of the participants who had adverse reactions. This means adverse reactions happened in 2 of the 9 participants in this study:

- There was 1 participant who had an adverse reaction of vomiting.
- There was 1 participant who had adverse reactions of redness at the site of an injection and headache with a medical procedure.

None of the participants left the study due to adverse reactions.

How has this study helped patients and researchers?

The results of this study have helped researchers learn about the safety of lacosamide given through an IV infusion to Japanese 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 one study. Other studies may provide new information or different results.

At the time that this study ended, further clinical studies with lacosamide were planned.

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

Where can I learn more about this study?

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

- www.clinicaltrials.gov/ct2/show/study/NCT02192814

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

Study Information

Protocol number: EP0024

Study Sponsor: UCB Japan Co. Ltd. sponsored this study. It is now called UCB Biopharma SPRL. It is referred to as UCB in this summary.

Treatment Studied: lacosamide

Short Study Title: This study was done to learn about the safety of lacosamide given through a vein in Japanese people with epilepsy.

Full Study Title: A Multicenter, Open-label Study to Evaluate the Safety and Tolerability of Intravenous Lacosamide as Replacement for Oral Lacosamide in Japanese Adults With Partial-onset Seizures With or Without Secondary Generalization

National Clinical Study number: NCT02192814

Glossary

Headache with a medical procedure:	Also called “procedural headache”
Redness at the site of an injection:	Also called “injection site erythema”

Last updated on [05 March 2019].

