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Study Sponsor:	UCB Biosciences, Inc.
Treatment Studied:	Lacosamide
Protocol Number:	EP0034
Short Study Title:	A study to learn about the long-term safety of lacosamide in children and adolescents 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 children and adolescents with epilepsy. Lacosamide is also called VIMPAT® or SPM 927.

This is a summary of the main results of this study. This study is sometimes called the EP0034 study. An independent, non-profit organization helped prepare this summary of the study results, which included feedback from patients.

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 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 has questions about the results, please speak with study staff.

Overview of this study

Why was the research needed?

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Researchers are looking for a way to treat epilepsy in children and adolescents. Before a treatment is available for all patients, researchers do clinical studies to find out how the treatment works and how safe it is.

What treatments did the participants take?

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The participants in this study took lacosamide.

What were the results of this study?

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

- **What medical problems did the participants have during the study?**
  There were **77.2%** of participants who had medical problems during the study. This was **417 out of 540** participants.

- **What medical problems did the study doctors report as possibly related to the study treatment?**
  There were **21.1%** of participants who had medical problems that the study doctors reported as possibly related to the study treatment. This was **114 out of 540** participants.

More details about the results of this study are included later in this summary.

Where can I learn more about this study?

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You can find more information about this study on the websites listed on the last page. If a full report of the study results is available, it can also be found on those websites.

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 about the safety of lacosamide in a large number of children and adolescents living with epilepsy.

Epilepsy is a brain condition that causes seizures. There are several types of seizures a person with epilepsy can have. A “partial-onset seizure” happens when unusual electrical activity starts in 1 part of the brain. A person experiencing a partial-onset seizure may not lose consciousness, but they may have muscle jerking and a loss of awareness of their surroundings. This can impact a person’s daily life, safety, and wellbeing. A partial-onset seizure can also change into a type of seizure called a “generalized seizure”. A generalized seizure can cause a loss of consciousness.

Someone with epilepsy may take daily medicine to control and stop most or even all of their seizures. There are several epilepsy medicines that help control seizures, but they do not always work well in all patients. In some patients, these medicines also cause too many side effects.

Lacosamide is a treatment that is designed to stop the unusual electrical activity in the brain that causes partial-onset seizures. Studies in adults and older adolescents with epilepsy have confirmed that the treatment works. Researchers now want to find out whether lacosamide works, and about its safety, in younger adolescents and children. Other studies have helped researchers learn more about how well lacosamide works in children and young adolescents. The researchers in this study wanted to learn more about the long-term safety of lacosamide for children and adolescents with epilepsy, who are 17 years of age and below.

What were the main questions studied?

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

- What medical problems did the participants have during the study?
- What medical problems did the study doctors report as possibly related to the study treatment?

Who participated in the study?

There were 540 males and females with epilepsy who participated in this study. They were a little under 3 months to 17 years old when they joined.

The study included participants in 35 countries:

Country	Number of participants
Argentina	9
Australia	6
Belgium	5
Brazil	6
Bulgaria	1
China	14
Colombia	1
Croatia	20
Czech Republic	9
Estonia	3
France	4
Georgia	47

Country	Number of participants
Greece	2
Hungary	51
Israel	8
Italy	13
Latvia	12
Lithuania	4
Mexico	36
Moldova	2
Montenegro	2
Philippines	2
Poland	33
Portugal	1

Country	Number of participants
Romania	24
Russia	29
Serbia	19
Slovakia	14
Slovenia	3
South Korea	17
Taiwan	16
Thailand	34
Ukraine	74
United Kingdom	2
United States	17

In this study, the researchers planned to include participants living with epilepsy who had participated in and completed 1 of 2 previous clinical studies called SP0967 and SP0969. Those studies looked at how well lacosamide worked and at its safety over a short period of time in children and adolescents with epilepsy.

Each participant was in this study for about 2 years, but the whole study lasted for a little less than 8 years. This study started in August 2014 and ended in April 2022.

What treatment did the participants take?

The participants in this study took lacosamide by mouth twice a day, either as a tablet or as a liquid. The study doctors decided who took the tablet and who took the liquid. The dose of lacosamide the participants took depended on their body weight.

The participants and their caregivers, study doctors, study staff, and UCB staff knew that all the participants in this study were taking lacosamide.

The chart below shows the treatment the researchers planned to study:

	Lacosamide
	540 participants
	Lacosamide as a tablet or as a liquid by mouth
	Twice a day, once in the morning and once in the evening
	Participants took lacosamide for about 2 years

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What happened during the study?

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

At the beginning of the study, the participants visited their clinic 1 time. Some participants decided to join the study, and some participants' parents or caregivers decided to let them join. 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.

While taking study treatment, the participants visited the clinic at least 13 times and had 11 telephone calls with the study team. The participants took lacosamide 2 times a day. The study doctors kept track of any medical problems reported by the participants or observed by the doctors or study staff. This part of the study lasted for 2 years.

During the study, the study doctors:

Asked the participants, or their parents or caregivers, about any medicines they were taking and any medical problems

Did physical exams and checked the participants' vital signs

Did neurological exams

Checked the participants' heart health using an electrocardiogram, also called an ECG, at some visits

Took blood and urine samples from the participants at some visits

Asked the participants, or their parents or caregivers, questions to learn about the participants' mental health and wellbeing

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The participants, or their parents or caregivers:

Kept track of their seizures every day using a diary

Continued taking their usual anti-seizure medicines during the study, and were able to change how much or what type of anti-seizure medicine they took

Completed questionnaires about the participants' daily activities, abilities, and mental and physical development

After taking study treatment, the participants visited the clinic 2 times and had a final telephone call over a period of 1 month. During this part, the dose of lacosamide was slowly decreased until the participants stopped taking it. At the 2 visits, the study doctors did some of the tests and measurements that were done during the study. They checked the participants' health and asked about any medical problems they were having.

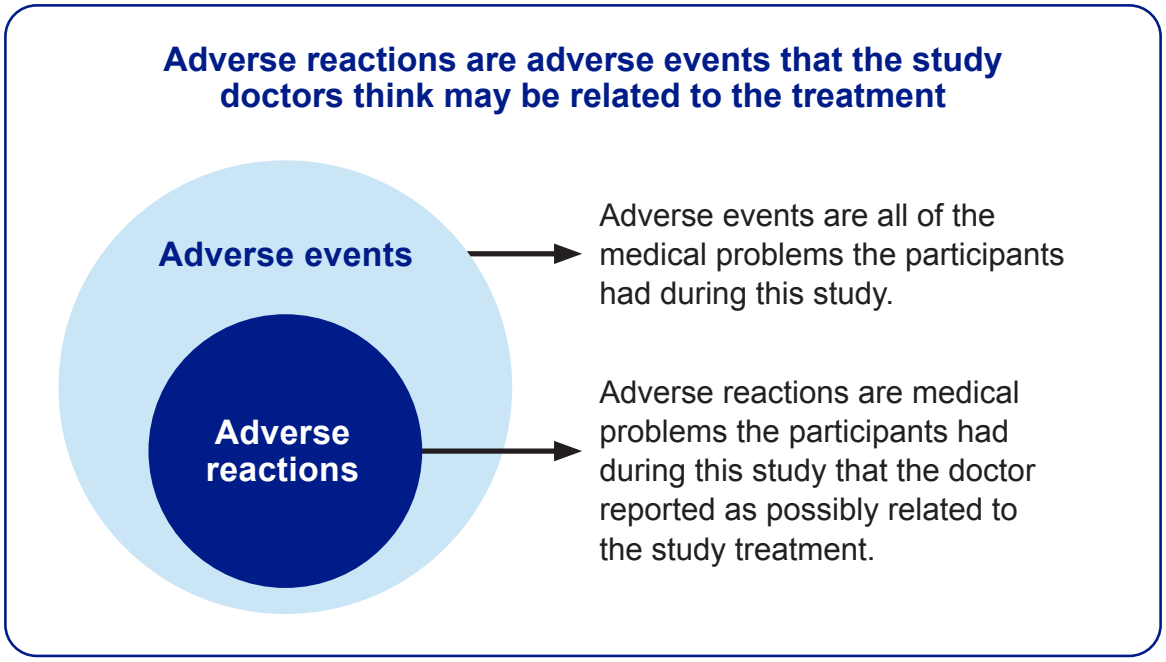
What were the results of this study?

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.

What medical problems did the participants have during the study?

In this summary, there is information about 2 different types of medical problems that the participants had during the study. An **adverse event** is **any** medical problem that a participant has during a study. Doctors keep track of all adverse events that happen in studies, whether or not these may be related to the study treatment. An **adverse reaction** is different from an adverse event because it is reported by the doctor as **possibly related** to the study treatment. An adverse event or adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.



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The information below is a summary of the **adverse events** that happened in this study.

Adverse events in this study	
	Lacosamide (540 participants)
How many participants had serious adverse events?	20.6% (111 participants)
How many participants had adverse events?	77.2% (417 participants)
How many participants left the study due to adverse events?	4.1% (22 participants)

The most common serious adverse events were:

- Seizure, also called “convulsion”
- Lung infection, also called “pneumonia”
- Vomiting
- Seizures that last too long or that happen in a short amount of time, also called “status epilepticus”
- Epilepsy

The most common adverse events were:

- Fever, also called “pyrexia”
- Infection of the nose, sinuses, and throat, also called “upper respiratory tract infection”
- Vomiting
- Inflammation of the nose and throat area, also called “nasopharyngitis”
- Seizure, also called “convulsion”
- Diarrhea
- Inflammation of the throat, also called “pharyngitis”
- Cough
- Infection of the main airways of the lungs, also called “bronchitis”
- Sleepiness, also called “somnolence”
- Flu, also called “influenza”
- Headache

What medical problems did the study doctors report as possibly related to the study treatment?

This section is a summary of the medical problems that the participants had during the study that the doctors reported as **possibly related** to the study treatment. These medical problems are called **"adverse reactions"**.

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 treatment. The results from several studies are often needed to decide if a treatment causes an adverse reaction. Always talk to a doctor before making any treatment decisions.

Some of the adverse reactions listed below may also be listed in the adverse events section earlier in this summary.

Did any adverse reactions happen during this study?

The table below shows how many participants had **adverse reactions** during the study.

Adverse reactions in this study

	Lacosamide (540 participants)
How many participants had serious adverse reactions?	1.7% (9 participants)
How many participants had adverse reactions?	21.1% (114 participants)
How many participants left the study due to adverse reactions?	1.7% (9 participants)

What serious adverse reactions did the participants have?

The table below shows the serious adverse reactions that happened during the study.

Serious adverse reactions in this study

	Lacosamide (540 participants)
Nausea	0.4% (2 participants)
Abnormal liver function test	0.2% (1 participant)
Confusion about one's surroundings, also called "disorientation"	0.2% (1 participant)
Dizziness	0.2% (1 participant)
Epilepsy	0.2% (1 participant)
Indigestion, also called "dyspepsia"	0.2% (1 participant)
Mental health disorder affecting thinking abilities, also called "cognitive disorder"	0.2% (1 participant)
Problems with movement, also called "motor dysfunction"	0.2% (1 participant)
Reduced eating, also called "hypophagia"	0.2% (1 participant)
Seizure, also called "convulsion"	0.2% (1 participant)
Vomiting	0.2% (1 participant)

None of the participants died due to serious adverse reactions.

What adverse reactions did the participants have?

The table below shows the **adverse reactions** that happened in 5 or more participants during the study. There were other adverse reactions, but these happened in fewer participants.

Most common adverse reactions in this study

	Lacosamide (540 participants)
Sleepiness, also called “somnolence”	3.0% (16 participants)
Dizziness	2.6% (14 participants)
Vomiting	2.6% (14 participants)
Seizure, also called “convulsion”	1.7% (9 participants)
Tiredness, also called “fatigue”	1.3% (7 participants)
Aggression	0.9% (5 participants)
Double vision, also called “diplopia”	0.9% (5 participants)
Increased number of a type of white blood cells called “eosinophils”, also called “eosinophil count increased”	0.9% (5 participants)
Nausea	0.9% (5 participants)
Weakness or lack of energy, also called “asthenia”	0.9% (5 participants)

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What did the researchers learn from this study?

The results of this study have helped researchers learn more about using lacosamide in children and adolescents living 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.

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.

At the time this document was approved, further clinical studies with lacosamide were not planned.

Where can I learn more about this study?

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

- http://www.clinicaltrials.gov/ct2/show/NCT01964560?term=NCT01964560
- www.clinicaltrialsregister.eu/ctr-search/search?query=2012-005012-26

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

Study Information

Protocol Number: EP0034

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

Full Study Title: A Multicenter, Open-label, Long-term Extension Study to Investigate the Efficacy and Safety of Lacosamide as Adjunctive Therapy in Pediatric Subjects With Epilepsy With Partial-Onset Seizures

National Clinical Study Number: NCT01964560

EudraCT Number: 2012-005012-26

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.

This summary was last updated on 19 September 2022.
The final clinical study report is dated 28 July 2022.