Clinical Study Results

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Study Sponsor: UCB Pharma, Inc.

Treatment Studied: Levetiracetam

Protocol Number: N159

Short Study Title: A study to learn if levetiracetam reduced seizures in children with epilepsy

Thank you!

UCB thanks all the participants of this study and their caregivers. All the participants and their caregivers helped the researchers learn more about using levetiracetam in children with epilepsy. Levetiracetam is also called Keppra®.

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 participated in this study and have questions about the study 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 levetiracetam worked in a large number of children 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. The symptoms of seizures can be different for each person but often include uncontrollable shaking and loss of consciousness.

Epileptic seizures that start in 1 area of the brain are known as "partial onset" seizures. In this study, the researchers wanted to find out if levetiracetam helped reduce partial onset seizures in participants with epilepsy.

What were the main questions studied?

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

- Did levetiracetam affect how many seizures the participants had per week?
- What medical problems did the study doctors think might be related to the study treatments?

Who participated in the study?

There were 198 boys and girls who participated in this study and were planned to take study treatment. The participants were 3 to 17 years old.

The study included participants who took study treatment in 2 countries: Canada and the United States.

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

- Were already taking 1 or 2 epilepsy medications but were still having uncontrolled seizures
- Had at least 4 uncontrolled seizures within the first 4 weeks, and 4 more uncontrolled seizures within the next 4 weeks, before starting study treatment

Each participant was in the study for about 6 months, but the whole study lasted for 3.5 years. The study started in September 1999 and ended in March 2003.

What treatments did the participants take?

The participants in this study took either levetiracetam or a placebo as tablets by mouth. The placebo tablets looked like the levetiracetam tablets but did not have any levetiracetam in them. The researchers used the placebo to help make sure the effects they found in the study were actually caused by levetiracetam. All of the participants also took their regular epilepsy medication throughout the study.

None of the participants, caregivers, study doctors, or study staff knew what treatments 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 levetiracetam or the placebo. This helped make sure the treatments were chosen fairly and comparing the results for the treatments was as accurate as possible.

The dose of levetiracetam was measured in milligrams per kilogram of body weight, also known as mg/kg. During the first 4 weeks, the participants who took levetiracetam slowly had their dose increased from 0 mg/kg to 60 mg/kg. After the first 4 weeks, the participants could have their dose decreased if the study doctors thought it was needed.

In this study:

- 101 participants were planned to take levetiracetam
- 97 participants were planned to take the placebo

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

	Levetiracetam	Placebo
	101 participants	97 participants
	Up to 60 mg/kg of levetiracetam as tablets	Tablets that looked like levetiracetam
	Twice a day for up to 20 weeks	Twice a day for up to 20 weeks

What happened during this study?

Before taking study treatment, the participants and their caregivers visited their clinic 2 times. Each participant's parent or caregiver learned about the study and decided to let the participant 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 8 weeks. The participants also took their regular epilepsy medication. At some of these visits, the study doctors:

	Kept track of any medical problems reported by the participants or their caregivers, or observed by the study doctors or study staff
	Took blood and urine samples
	Checked the participants' brain health using an electroencephalogram, also called an EEG
	If needed, took pictures of each participant's brain using CT or MRI scans

The study doctors also did some of these tests and measurements at different visits throughout the rest of the study.

While taking study treatment, the participants and their caregivers visited their clinic 9 times. This part of the study lasted for 20 weeks.

The participants:	
	Took levetiracetam or the placebo twice a day
	Continued taking their regular epilepsy medication
	Kept track of their seizures in a diary

The study doctors also:	
	Checked the participants' heart health using an electrocardiogram, also called an ECG
	Asked the participants about their symptoms and quality of life

After taking study treatment, the participants were given the option to immediately join a different study for levetiracetam. In that study, all of the participants were planned to take levetiracetam. The participants who were taking levetiracetam in this study but chose not to join the new study had their dose of levetiracetam slowly decreased until they were taking none. The participants who did not join the new study visited their clinic up to 1 time. This part of the study lasted for 6 weeks. 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.

Did levetiracetam affect how many seizures the participants had per week?

Yes. Overall, the participants who took levetiracetam had fewer seizures per week than the participants who took the placebo.

To answer this question, the study doctors counted the number of seizures that the participants had during the study. They calculated the average number of seizures per week. Then, the researchers compared the average number of seizures per week in the participants who took levetiracetam and in the participants who took the placebo.

On average, they found that the participants who took levetiracetam had **26.8% fewer** seizures per week than the participants who took the placebo.

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”.

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:

- None of the participants who took levetiracetam.
- 1.0% of the participants who took the placebo. This was 1 out of 97 participants.

What serious adverse reactions did the participants have?

The only serious adverse reaction that happened during this study was a seizure.

None of the participants died due to serious adverse reactions.

How many participants had any adverse reactions?

Adverse reactions happened in:

- 55.4% of the participants who took levetiracetam. This was 56 out of 101 participants.
- 40.2% of the participants who took the placebo. This was 39 out of 97 participants.

What adverse reactions did the participants have?

The table below shows the adverse reactions that happened in 5.0% or more of participants in either treatment group. This means they happened in at least 5 out of every 100 participants in either treatment group. There were other adverse reactions, but these happened in fewer participants.

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

Adverse reaction	**Levetiracetam** (out of 101 participants)	**Placebo** (out of 97 participants)
Sleepiness	16.8% (17)	7.2% (7)
Feeling hostile	9.9% (10)	6.2% (6)
Anorexia eating disorder	9.9% (10)	5.2% (5)
Feeling nervous	7.9% (8)	1.0% (1)
Weakness	6.9% (7)	1.0% (1)
Personality disorder	5.9% (6)	6.2% (6)
Mood changes	5.0% (5)	4.1% (4)
Headache	5.0% (5)	2.1% (2)
Feeling agitated	5.0% (5)	0.0% (0)
Seizure	3.0% (3)	7.2% (7)

How has this study helped patients and researchers?

The results of this study have helped researchers learn more about using levetiracetam in children 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 own health or situation, please contact your doctor.

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

At the time this study ended, further clinical studies in epilepsy with levetiracetam were planned.

Where can I learn more about this study?

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

- https://clinicaltrials.gov/ct2/show/NCT00615615

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

Study Information

Protocol Number: N159

Study Sponsor: UCB Pharma, Inc. sponsored this study. They are referred to as UCB in this summary. UCB Pharma, Inc., is now called UCB, Inc.

Full Study Title: Evaluation of The Efficacy and Tolerability of Levetiracetam Add-On Treatment in Refractory Pediatric Patients With Partial Onset Seizures: A 28-Week Double-Blind, Placebo-Controlled Multi-center Trial

National Clinical Study Number: NCT00615615

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.

Glossary

Description	Also called
Mood changes	Emotional lability
Seizure	Convulsion
Sleepiness	Somnolence
Weakness	Asthenia

This summary was last updated on 20 December 2021.
The final clinical study report is dated 26 October 2004.