

Clinical Study Results

Study Sponsor: UCB Biopharma SRL

Treatment Studied: Levetiracetam

Protocol Number: N01009

Short Study Title: A study to learn if levetiracetam reduces seizures in very young children with epilepsy

Thank you!

UCB thanks all the participants of this study and their caregivers. All the participants and caregivers helped the researchers learn about using levetiracetam in very young 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 doctor or your child's doctor.

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 participants with epilepsy. They also wanted to learn if the participants had any medical problems during the study.

Epilepsy is a neurological condition 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 cannot be controlled by epilepsy medications are also known as refractory seizures or uncontrolled seizures.

In this study, researchers wanted to find out if taking levetiracetam helped reduce uncontrolled seizures in very young children with epilepsy.

What were the main questions studied?

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

- Did levetiracetam help reduce how often the participants had uncontrolled seizures?
- What medical problems did the participants have during the study?

Who participated in the study?

There were 116 very young boys and girls who participated in this study and took study treatment. They were 1 month old to under 4 years old.

The study included participants who took study treatment in 13 countries: Belgium, Brazil, the Czech Republic, France, Germany, Hungary, Italy, Mexico, Poland, Romania, Russia, the United Kingdom, and the United States.

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

- Were already taking 1 or 2 other epilepsy medications but were still having uncontrolled seizures
- Had at least 2 seizures per week within the 2 weeks before starting the study
- Had at least 2 seizures within the 2 days before starting the study that the researchers measured

Each participant was in the study for just over a month, but the whole study lasted for about 2 years and 3 months. The study started in October 2004 and ended in January 2007.

What treatments did the participants take?

The participants in this study took either levetiracetam or a placebo in addition to their regular epilepsy medication. Levetiracetam and the placebo were taken as a liquid by mouth once in the morning and once in the evening for about 3 weeks.

The placebo liquid looked and tasted like the levetiracetam liquid but did not have any levetiracetam in it. The researchers used the placebo to help make sure the effects of levetiracetam they found in the study were actually caused by it.

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None of the participants, caregivers, study doctors, or study staff knew what treatment 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 chart below shows the treatments the researchers studied:

	60 participants took levetiracetam
	56 participants took the placebo
	The participants took 2 doses of levetiracetam or the placebo every day for about 3 weeks
	Levetiracetam and the placebo were taken as a liquid by mouth

What were the doses of levetiracetam?

The doses of levetiracetam were measured in milligrams per kilogram of body weight per day, also known as mg/kg/day. The participants took a minimum dose and a maximum dose.

For participants who were 1 month old to under 6 months old:

- The minimum dose was 20 mg/kg/day
- The maximum dose was 40 mg/kg/day

For participants who were 6 months old to under 4 years old:

- The minimum dose was 25 mg/kg/day
- The maximum dose was 50 mg/kg/day

The participants who took levetiracetam started taking the minimum dose on Day 1 of the study. On the morning of Day 2, their dose was increased to the maximum dose. On the evening of Day 6, their dose was decreased back to the minimum dose. The participants continued taking the minimum dose until they finished taking study treatment on the morning of Day 20.

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The chart below shows when the participants took the different doses of levetiracetam.

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Maximum dose																				
Minimum dose																				

What happened during the study?

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

Before joining the study, the participants and their caregivers visited their clinic at least 1 time. 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 for 1 week.

At these visits, the study doctors:

-  Kept track of any medical problems reported by the participants or their caregivers, or observed by the doctors or study staff
-  Checked the participants’ heart health using an electrocardiogram, also called an ECG
-  Took blood samples
-  Checked the participants’ brain health using computed tomography or magnetic resonance imaging scans, also called CT or MRI scans

During the study, the participants and their caregivers stayed overnight at their study site for 1 week. The participants started taking levetiracetam or the placebo on Day 1. After the first week, they continued taking levetiracetam or the placebo at home for 2 weeks.

During the 2 days before the participants started taking study treatment, the study doctors took a video recording of the participants for 48 hours. They did this along with a type of brain scan called an electroencephalogram, also called an EEG. These measurements together are called a video-EEG, which is used to measure seizures. The study doctors also did a video-EEG on Days 4 and 5 of taking study treatment.

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The participants:



Stayed overnight at their study site for about 1 week



Took 2 doses of levetiracetam or the placebo every day for about 3 weeks



Continued taking their regular epilepsy medication

The study doctors:



Kept track of any medical problems reported by the participants or caregivers, or observed by the doctors or study staff



Took blood samples



Did a video-EEG to measure the participants' seizures on the 2 days before study treatment and on Days 4 and 5 during study treatment

About 4 days after the participants stopped taking study treatment, the participants and their caregivers visited their clinic 1 time. 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.

The results below include 109 out of 116 participants. This is because some participants did not finish all of the treatments or measurements.

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Did levetiracetam help reduce how often the participants had uncontrolled seizures?

Yes. The researchers found that levetiracetam reduced how often the participants had uncontrolled seizures compared with the placebo.

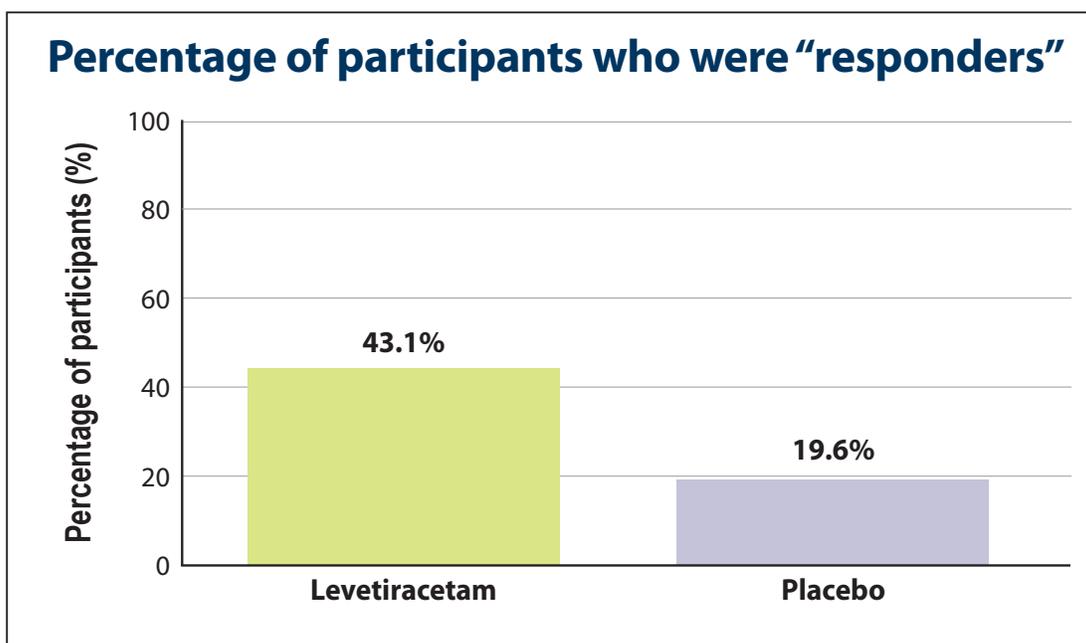
To answer this question, the study doctors took a video recording of the participants for 48 hours. They did this along with a type of brain scan called an electroencephalogram, also called an EEG. These measurements together are called a video-EEG. Using the video-EEG, the doctors looked at what type of seizures the participants had and counted how often the participants had uncontrolled seizures. They compared the results from the video-EEG done during the 2 days before the participants got study treatment with the video-EEG done during Days 4 and 5 of taking study treatment.

If the participants' number of uncontrolled seizures was reduced by 50% or more from before taking study treatment to after taking study treatment, they were known as "responders."

The researchers found that:

- 43.1% of participants taking levetiracetam were "responders". This was 25 out of 58 participants.
- 19.6% of participants taking the placebo were "responders". This was 10 out of 51 participants.

The graph below shows these 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 study doctors thought might be related to the treatments. These medical problems are called “adverse reactions.”

In this study, an adverse reaction is considered “serious” when it puts the participant’s life at risk, requires hospitalization, causes disability, or may have turned into 1 of these problems if not treated.

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. Always talk to a doctor before making any treatment decisions.

How many participants had serious adverse reactions?

None of the participants had serious adverse reactions.

How many participants had any adverse reactions?

In this study, adverse reactions happened in:

- 21.7% of participants who took levetiracetam during the study. This was 13 out of 60 participants.
- 7.1% of participants who took the placebo during the study. This was 4 out of 56 participants.

What adverse reactions did the participants have?

The table below shows the adverse reactions that happened in 5.0% or more participants in either of the treatment groups. This means they happened in at least 1 out of every 20 participants in either of the treatment groups. There were other adverse reactions, but these happened in fewer participants.

The most common adverse reaction was sleepiness.

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

Adverse reaction	Levetiracetam (out of 60 participants)	Placebo (out of 56 participants)
<u>Sleepiness</u>	8.3% (5)	1.8% (1)
Irritability	5.0% (3)	0.0% (0)

How has this study helped patients and researchers?

The results of this study have helped researchers learn more about using levetiracetam in very young 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 or your child's health or situation, please contact your doctor or your child's doctor.

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

When this study ended, further clinical studies with levetiracetam were 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/study/NCT00175890>
- www.clinicaltrialsregister.eu/ctr-search/search?query=2004-000199-14

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

Study Information

Protocol Number: N01009

Study Sponsor: UCB Biopharma SRL sponsored this study. It is referred to as UCB in this summary. UCB Biopharma SRL was previously called UCB Pharma Inc.

Full Study Title: A Double-Blind, Randomized, Multicenter, Placebo-Controlled, In-Patient, Maximum 34 Day Study of Levetiracetam Oral Solution (20-50 mg/kg/day) as Adjunctive Treatment of Refractory Partial Onset Seizures in Pediatric Epileptic Subjects Ranging in Age from 1 Month to Less Than 4 Years of Age

National Clinical Study Number: NCT00175890

EudraCT Number: 2004-000199-14

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
Sleepiness	Somnolence



This summary was last updated on 20 November 2020.
The final clinical study report is dated 27 August 2007.