Clinical Study Results

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Study Sponsor: UCB, Inc.

Treatment Studied: Levetiracetam

Protocol Number: N01103

Short Study Title: A study to learn if levetiracetam affected attention and memory in 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 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 need medical advice, please contact your 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 small 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 may include loss of consciousness.

In this study, the researchers wanted to find out if levetiracetam affected attention and memory in children with epilepsy. The participants in this study had “partial onset” seizures, which are epileptic seizures that start in one area of the brain.

What were the main questions studied?

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

- Did levetiracetam affect the participants’ attention and memory?
- What medical problems did the study doctors think might be related to the study treatments?

Who participated in the study?

There were 99 boys and girls who participated in this study and were planned to take study treatment. The participants were 4 to 16 years old.

The study included participants who were planned to take study treatment in 3 countries: Canada, South Africa, 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 1 uncontrolled seizure within 4 weeks before joining the study

Each participant was in the study for about 4 months, but the whole study lasted for 2.5 years. The study started in September 2004 and ended in March 2007.

What treatments did the participants take?

The participants took levetiracetam or a placebo as a tablet or a liquid by mouth, twice a day for 16 weeks. The placebo tablets and liquid looked like the levetiracetam tablets and liquid 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 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.

In this study:

- 65 participants were planned to take levetiracetam
- 34 participants were planned to take the placebo

The doses of levetiracetam were measured in milligrams per kilogram per day, also known as “mg/kg/d”.

During the first 4 weeks of taking the study treatment, the participants who took levetiracetam slowly had their dose increased until they were taking 60 mg/kg/d. After the first 4 weeks, the participants could have their dose decreased if the study doctors thought it was needed.

During the last 4 weeks of taking study treatment, the participants who took levetiracetam slowly had their dose decreased until they were taking none.

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

	Levetiracetam	**Placebo**
	65 participants	34 participants
	Up to 60 mg/kg/d of levetiracetam as tablets or liquid by mouth	Tablets or liquid that looked like levetiracetam
	Twice a day for 16 weeks	

What happened during this study?

Before taking study treatment, the participants and their caregivers visited their clinic 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 1 week. 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 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
	At some visits, checked the participants' heart health using an electrocardiogram, also called an ECG
	Used various scores and clinical measurements to check the participants' attention and memory

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 up to 6 times and had 1 phone call. This part of the study lasted for 16 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:	
	Asked the participants about their symptoms and quality of life

After taking study treatment, the participants visited their clinic 1 time. This part of the study lasted for 2 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.

The results below are for the participants who took enough of their study treatments and completed enough of the measurements. This was:

- 46 out of 65 participants in the levetiracetam group
- 27 out of 34 participants in the placebo group

Did levetiracetam affect the participants' attention and memory?

No. Overall, the researchers found that levetiracetam did not affect the participants' attention and memory compared to the placebo.

To answer this question, the researchers used a clinical measurement called the "Leiter-R Attention and Memory Screen Composite Score". This score is calculated by how well the participants are able to complete learning activities to test their attention and memory. A higher score means better attention and memory.

The researchers looked at the average change in the score from before the participants took study treatment and after 12 weeks of taking study treatment. The researchers compared the average change in score between the participants who took levetiracetam and the participants who took the placebo.

Overall, the researchers found that the average change in attention and memory score between the participants who took levetiracetam and the participants who took the placebo was **about the same.**

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.

The results below are for the 98 out of 99 participants who took at least 1 dose of study treatment.

How many participants had serious adverse reactions?

None of the participants in this study had serious adverse reactions.

None of the participants died due to serious adverse reactions.

How many participants had any adverse reactions?

Adverse reactions happened in:

- 51.6% of the participants who took levetiracetam. This was 33 out of 64 participants.
- 41.2% of the participants who took the placebo. This was 14 out of 34 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. There were other adverse reactions, but those happened in fewer participants.

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

Adverse reaction	**Levetiracetam** (out of 64 participants)	**Placebo** (out of 34 participants)
Sleepiness	14.1% (9)	8.8% (3)
Aggression	10.9% (7)	8.8% (3)
Fatigue	9.4% (6)	8.8% (3)
Headache	7.8% (5)	5.9% (2)
Fidgeting or moving around without purpose	6.3% (4)	11.8% (4)
Problems with falling asleep or staying asleep	6.3% (4)	2.9% (1)
Upper stomach pain	6.3% (4)	2.9% (1)
Change in mood	6.3% (4)	none
Dizziness	3.1% (2)	5.9% (2)
Increased appetite	none	5.9% (2)

How has this study helped patients and researchers?

The results of this study have helped researchers learn more about using levetiracetam alone and with other epilepsy medications in people 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 1 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 people 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 websites listed below:

- https://clinicaltrials.gov/ct2/show/NCT00105040

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

Study Information

Protocol Number: N01103

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

Full Study Title: A 19-week, Randomized, Double-blind, Multicenter, Placebo-controlled Safety Study to Evaluate the Cognitive and Neuropsychological Effects of Levetiracetam 20-60 mg/kg/d, Divided in Twice Daily Dosing, as Adjunctive Treatment in Children 4-16 Years Old, Inclusive, with Partial Onset Seizures

National Clinical Study Number: NCT00105040

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
Fidgeting or moving around without purpose	Psychomotor hyperactivity
Problems with falling asleep or staying asleep	Insomnia
Sleepiness	Somnolence

This summary was last updated on 09 May 2022.
The final clinical study report is dated 04 January 2008.