

Clinical Study Results



Study Sponsor: UCB Biopharma SRL

Treatment Studied: Levetiracetam

Protocol Number: N01102

Short Study Title: A study to learn if levetiracetam reduced seizures in Chinese participants 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 Chinese participants 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 results, please speak with a 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 participants 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 cannot be controlled by epilepsy medications are also known as refractory seizures or uncontrolled seizures. Researchers think that taking levetiracetam may help reduce uncontrolled seizures.

In this study, the researchers wanted to find out if levetiracetam helped reduce uncontrolled seizures in Chinese 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 participants have during the study?

Who participated in the study?

There were 206 males and females with epilepsy in China who participated in this study and took study treatment. The participants were 15 to 70 years old.

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 8 uncontrolled seizures within the 8 weeks before starting the study

Each participant was in the study for about 5 months, but the whole study lasted for 10 months. The study started in July 2004 and ended in May 2005.

What treatments did the participants take?

The participants in this study took either levetiracetam or a placebo in addition to their regular epilepsy medication. They took levetiracetam or the placebo as tablets by mouth once in the morning and once in the evening for about 20 weeks. 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.

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:

- 103 participants took levetiracetam
- 103 participants took the placebo

The doses of levetiracetam were measured in milligrams per day, also known as mg/day.

The participants who took levetiracetam took:





- 1,000 mg/day of levetiracetam for the first 2 weeks of taking study treatment
- 2,000 mg/day of levetiracetam for the next 2 weeks
- 3,000 mg/day of levetiracetam for the next 12 weeks. During this time, the study doctors could decrease the participants' dose to 2,000 mg/day of levetiracetam if they thought it was needed.

After this, these participants either:

- Had their dose slowly decreased over 4 weeks until they were not taking any levetiracetam
- Started taking levetiracetam as part of their regular treatment

Clinical Study Results



The chart below shows the treatments the researchers studied:

	103 participants took levetiracetam <ul style="list-style-type: none">• 1,000 mg/day for 2 weeks• 2,000 mg/day for 2 weeks• 3,000 mg/day for 12 weeks• Slowly decreased dose to 0 mg/day over 4 weeks, or started taking levetiracetam as part of their regular treatment
	103 participants took the placebo
	The participants took levetiracetam and the placebo as tablets by mouth
	The participants took 2 doses of levetiracetam or the placebo each day for about 20 weeks

What happened during the study?

Before joining the study, the participants visited their clinic at least 1 time. Each participant or their caregiver learned about the study and decided that the participant would 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.




At this visit, 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



Clinical Study Results

During the study, the participants visited their clinic 5 times. They took levetiracetam or the placebo at home for about 20 weeks.

The participants:

	Took 2 doses of levetiracetam or the placebo each day for about 20 weeks
	Continued taking their regular epilepsy medication
	Kept track of their seizures in a diary

The study doctors:

	Kept track of any medical problems reported by the participants or observed by the study doctors or study staff and reduced the dose of levetiracetam if needed
	Took blood and urine samples

At the end of the study, the participants who took levetiracetam either had their dose slowly decreased over 4 weeks until they were taking none. Or, they continued to take levetiracetam as part of their regular treatment. The participants visited their clinic once during this 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 202 out of 206 participants. This is because some participants did not finish all of their treatments or study tests and measurements.

Clinical Study Results

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.

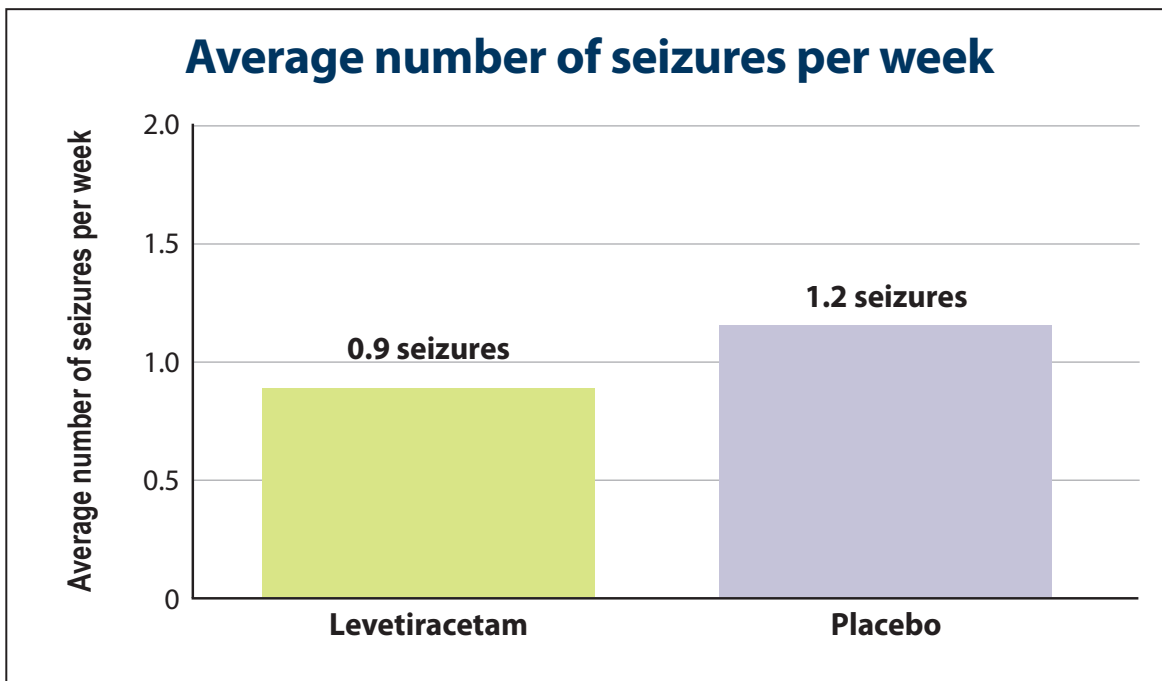
To answer this question, the study doctors counted the number of seizures the participants had during the study. Then, they estimated the average number of seizures per week. They compared the average number of seizures per week in the participants who took levetiracetam and in the participants who took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

Overall, the researchers found that the average number of seizures per week was:

- 0.9 seizures per week for the participants who took levetiracetam
- 1.2 seizures per week for the participants who took the placebo

This means that the percentage difference in the average number of seizures per week between the groups was 26.8%.

The chart 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.”

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 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 during this study.

How many participants had any adverse reactions?

- 42.7% of participants who took levetiracetam had adverse reactions during the study. This was 44 out of 103 participants.
- 41.7% of participants who took the placebo had adverse reactions during the study. This was 43 out of 103 participants.

What adverse reactions did the participants have?

The table below shows the adverse reactions that happened in 5% or more of 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.

Clinical Study Results

The most common adverse reaction was sleepiness.

Adverse reactions in 5% or more of participants in either treatment group

Adverse reaction	Levetiracetam (out of 103 participants)	Placebo (out of 103 participants)
<u>Sleepiness</u>	17.5% (18)	16.5% (17)
Decreased levels of <u>blood cells</u> that help form blood clots	9.7% (10)	9.7% (10)
Dizziness	2.9% (3)	7.8% (8)

How has this study helped patients and researchers?

The results of this study have helped researchers learn more about using levetiracetam in Chinese participants.

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 people who have epilepsy.

At the time 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 website listed below:

- www.clinicaltrials.gov/ct2/show/study/NCT00152373

If you have questions about this study, UCB contact information is available at:

www.ucb.com/UCBCares

Study Information

Protocol Number: N01102

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

Full Study Title: A Double-blind, Placebo-controlled, Randomized Study: 16-week Evaluation of the Efficacy and Safety of Levetiracetam (LEV) as Add-on Therapy in Adults and Adolescents Older than 16 Years Suffering from Partial Seizures

National Clinical Study Number: NCT00152373

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:
<u>Sleepiness</u>	“somnolence”
<u>Blood cells that help form blood clots</u>	“platelets”



This summary was last updated on 26 January 2021
The final clinical study report is dated 16 November 2005