

Clinical Study Results



Study Sponsor: UCB Biopharma SPRL

Treatment Studied: Levetiracetam

Protocol Number: N01375

Short Study Title: A study to learn how levetiracetam worked when taken by itself in Japanese participants with newly diagnosed epilepsy

Thank you!

UCB thanks all the participants of this study. All the participants helped the researchers learn more about using levetiracetam in people with epilepsy.

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 and the public. We hope this summary helps the participants 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 your study doctor or the 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 participants with recently diagnosed epilepsy. They also wanted to learn if the participants had any medical problems.

People with epilepsy have seizures that happen again and again. Seizures are caused by uncontrolled electrical activity in the brain.

Some seizures start in just 1 part of the brain. These are called focal seizures, also called partial onset seizures. The term focal seizures is used throughout this summary. The participants in this study had focal seizures.

Levetiracetam helps reduce uncontrolled electrical activity in the brain that causes seizures. At the start of this study, levetiracetam was not available in Japan as a treatment for people with epilepsy. In this study, the researchers wanted to learn if levetiracetam worked in Japanese adults with epilepsy.

What were the main questions studied?

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

- How many participants did not have seizures for 6 months in a row?
- What medical problems did the participants have during the study?

Who participated in the study?

The study included 71 male and female participants in Japan. They were 16 to 73 years old.

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

- Had at least 2 focal seizures in the year before they joined the study. The seizures had to be at least 48 hours apart.
- Had 1 of the seizures in the 3 months before they joined the study.
- Had never taken levetiracetam before.
- Weighed at least 40 kilograms.

Each participant could be in the study until the time that levetiracetam was available as a treatment in Japan for adults with focal seizures. The whole study lasted a little over 3 years. The study started in December 2011 and ended in April 2015.

What treatments did the participants take?

The participants in this study took levetiracetam as a pill. Doses were measured in milligrams, also called mg.

The researchers used a computer program to randomly choose the dose of levetiracetam the participants took. This helped make sure the treatments were chosen fairly.

The participants, study doctors, study staff, and UCB staff knew which dose of levetiracetam each participant took.





There were 71 participants who took levetiracetam during this study:

 61 participants were in the 1,000 to 2,000 mg each day treatment group

 10 participants were in the 3,000 mg each day treatment group

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






| | |
|---|--|
|  1,000 to 2,000 mg of levetiracetam each day |  3,000 mg of levetiracetam each day |
|  levetiracetam twice each day |  levetiracetam twice each day |

What happened during the study?



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

Before the study started, all the participants first learned about the study and then decided to join. This is called “informed consent.” The study doctors and study staff then asked about their medical history and checked their health to make sure they could be in the study.

During the study:



| | |
|---|--|
|  | The participants kept track of their seizures every day using diaries. |
|  | The participants had clinic visits about every 4 to 13 weeks. |
|  | The study doctors kept track of any medical problems reported by the participants or observed by the doctors or study staff. |
|  | The participants gave blood and urine samples at some clinic visits. |
|  | The participants had electrocardiograms, also called ECGs. These are tests that record the electrical activity in the heart. |

Before the main part of the study:



-  Some participants took 1,000 mg of levetiracetam each day for 1 week.
-  The rest of the participants started taking 1,000 mg of levetiracetam each day and slowly took a higher dose until they were taking 3,000 mg of levetiracetam each day. Once they reached 3,000 mg of levetiracetam each day, they kept taking it for 1 week.

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The main part of the study lasted up to 52 weeks. During this part:

-  Some participants took 1,000 mg of levetiracetam each day for up to 26 weeks. If they had a seizure, the study doctors could adjust their dose to 2,000 mg each day for up to 26 weeks.
-  The rest of the participants took 3,000 mg of levetiracetam each day for 26 weeks.

After the main part:

-  The participants who did not have a seizure during the main part while taking either their original or the adjusted dose of levetiracetam could stay in the study. They could take levetiracetam for at least another 26 weeks. The participants could take a dose as high as 3,000 mg of levetiracetam each day during this time.
-  Of the participants who did not stay in the study:
 - Those who were taking 1,000 mg of levetiracetam left the study right away.
 - Those who were taking more than 1,000 mg of levetiracetam took smaller amounts of levetiracetam until they were not taking it at all.

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.

How many participants did not have seizures for 6 months in a row?

The researchers wanted to learn the percentage of participants who did not have seizures for 6 months in a row while taking 1,000 to 2,000 mg of levetiracetam each day. The researchers wanted to know if the percentage was similar or higher than what is seen with current epilepsy treatments that work.

To find the percentage, the researchers asked the participants to record the number of seizures they had during the main part of the study. The researchers counted the number of participants with no seizures for 6 months in a row at their final dose of levetiracetam. They compared this to available treatments for epilepsy.

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Using mathematical methods, the researchers learned that levetiracetam helped control the participants' seizures about the same as or more than what is seen with current epilepsy treatments that work.

The researchers found that:

- 73.8% of the participants who took 1,000 to 2,000 mg of levetiracetam each day did not have seizures for 6 months in a row. This was 45 out of 61 participants.

The researchers also calculated the percentage for the 10 participants who took 3,000 mg of levetiracetam each day and had no seizures for 6 months in a row. But, this was not the main question this study was designed to answer. So, the results above are only for the participants who took 1,000 to 2,000 mg of levetiracetam each day.

What medical problems did the participants have?

This section is a summary of the medical problems the participants had during the study that the doctors thought might be related to the treatments. These medical problems are called "adverse reactions." Some participants had more than 1 adverse reaction.

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 one of these problems if not treated.

The adverse reactions shown in this summary 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.

How many participants had serious adverse reactions?

In this study, serious adverse reactions happened in:

- None of the participants who took 3,000 mg of levetiracetam each day. This was 0 out of 10 participants.
- 1.6% of the participants who took 1,000 to 2,000 mg of levetiracetam each day. This was 1 out of 61 participants.

The serious adverse reactions were irritability, and extreme moods, confusion, or not knowing what is real after a seizure.

None of the participants died due to serious adverse reactions during the study.

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How many participants had any adverse reactions?

In this study, adverse reactions that were serious or not serious happened in:

- 67.2% of the participants who took 1,000 to 2,000 mg of levetiracetam each day. This was 41 out of 61 participants.
- 40.0% of the participants who took 3,000 mg of levetiracetam each day. This was 4 out of 10 participants.

What adverse reactions did the participants have?

In this study, the most common adverse reaction for each study treatment was sleepiness.

The table below shows the adverse reactions that happened in 2 or more participants in either levetiracetam group. There were other adverse reactions during this study, but these happened in fewer participants.

Adverse reactions in 2 or more participants in either levetiracetam group

| | Levetiracetam 1,000 to 2,000 mg each day (out of 61 participants) | Levetiracetam 3,000 mg each day (out of 10 participants) |
|-----------------------------------|--|---|
| <u>Sleepiness</u> | 36.1% (22) | 20.0% (2) |
| <u>Feeling generally unwell</u> | 6.6% (4) | 0% (0) |
| Dizziness | 4.9% (3) | 0% (0) |
| <u>Numbness or sensation loss</u> | 3.3% (2) | 0% (0) |
| Irritability | 3.3% (2) | 0% (0) |

How has this study helped patients and researchers?

The results of this study have helped researchers learn more about using levetiracetam in people who have newly diagnosed epilepsy with focal seizures. The results might be used in other studies to compare levetiracetam with other treatments for people who have a similar condition.

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.

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 website listed below:

- <https://clinicaltrials.gov/ct2/show/NCT01506882?id=NCT01506882&rank=1>
- <https://www.clinicaltrialsregister.eu/ctr-search/trial/2014-004377-16/results>

If you have questions about this study, you can contact UCB by e-mail at datasharing@ucb.com.

Study Information

Protocol Number: N01375

Study Sponsor: UCB Biopharma SPRL sponsored this study. It was previously called UCB S.A. and is referred to as UCB in this summary.

Full Study Title: An open-label, randomized, multicenter study to evaluate the efficacy and safety of levetiracetam used as monotherapy in newly or recently diagnosed epilepsy patients aged older than or equal to 16 years with partial seizures

National Clinical Study Number: NCT01506882

EudraCT Number: 2014-004377-16

Thank you!

The 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

| | |
|--|------------------------------------|
| Extreme moods, confusion, or not knowing what is real after a seizure: | Also called “postictal psychosis.” |
| Feeling generally unwell: | Also called “malaise.” |
| Numbness or sensation loss: | Also called “hypoesthesia.” |
| Sleepiness: | Also called “somnolence.” |



This summary was last updated on 06 September 2019.
The final clinical study report is dated 15 September 2015.