

Clinical Study Results

Study Sponsor: UCB Japan, Co., Ltd

Treatment Studied: Levetiracetam

Protocol Number: N01378

Short Study Title: A study to learn about the safety of levetiracetam in participants with epilepsy when given as an IV infusion

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. 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 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 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 about the safety of levetiracetam in a small number of people with epilepsy when given through a needle into a vein, also known as an “IV infusion”. 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.

Levetiracetam is a treatment that is already available for people with epilepsy. It is normally taken as a tablet by mouth. Some people may not be able to take tablets because of stomach and intestine problems, or they may be too unwell to swallow. So, researchers are looking at giving levetiracetam as an IV infusion.

In this study, the researchers wanted to find out about the safety of levetiracetam when given as an IV infusion in participants with epilepsy.

What were the main questions studied?

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

- What medical problems did the participants have during the study?
- What medical problems did the study doctors think might be related to the study treatments?

Who participated in the study?

There were 16 men and women with epilepsy who participated in this study and were planned to get study treatment. They were 20 to 52 years old.

The study included participants who took study treatment in Japan.

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

- were already taking a steady dose of levetiracetam as a tablet
- were taking 1 to 3 other epilepsy medications

Each participant was in the study for about 1 month, but the whole study lasted for 7 months. The study started in July 2011 and ended in February 2012.




What treatments did the participants take?

All of the participants in this study got levetiracetam as an IV infusion twice a day for 4 days.

The participants, study doctors, study staff, and UCB staff knew that all the participants in this study were getting levetiracetam.






The participants got the same dose of levetiracetam that they were already getting before the study. After they finished getting all of their IV infusions, they went back to taking their regular tablets.

The chart below shows the treatments the researchers studied.

	16 participants
	Their regular dose of levetiracetam as IV infusions
	Twice a day for 4 days

What happened during this study?

Before taking study treatment, the participants visited their clinic 1 time. All the participants first learned about the study and then decided to join. This is called “informed consent”. Then, the study doctors and study staff asked the participants about their medical history and checked their health to make sure they could join the study. This part of the study lasted for 2 weeks. The participants took their regular epilepsy medication. 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
	Checked the participants' heart health using an electrocardiogram, also called an ECG
	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 stayed overnight at their clinic for 6 days. They got their IV infusions of levetiracetam twice a day for 4 days.

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.

What medical problems did the participants have during the study?

To answer this question, the doctors did tests and measurements before and after the participants got levetiracetam. The doctors did physical exams and tested the participants' blood and urine samples to check their overall health. They also did ECGs to check the participants' heart health. Overall, the researchers found that there were some small changes in the results of these tests and measurements. But, the researchers did not consider these to be meaningful.

The doctors also kept track of the “adverse events” that the participants had. An adverse event is any medical problem that participants have during a study. Doctors keep track of all the adverse events that happen in studies, even if they do not think the adverse events might be related to the study treatment. An adverse event is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

Adverse events may or may not be caused by the study treatments. The results from several studies are needed to decide if a treatment causes an adverse event. Later in this document, there will be a summary of the adverse events that the doctors thought might be related to the study treatments.

How many participants had serious adverse events?

None of the participants had serious adverse events.

How many participants had adverse events?

There were 31.3% of participants who had adverse events. This was 5 out of 16 participants.

What adverse events did the participants have?

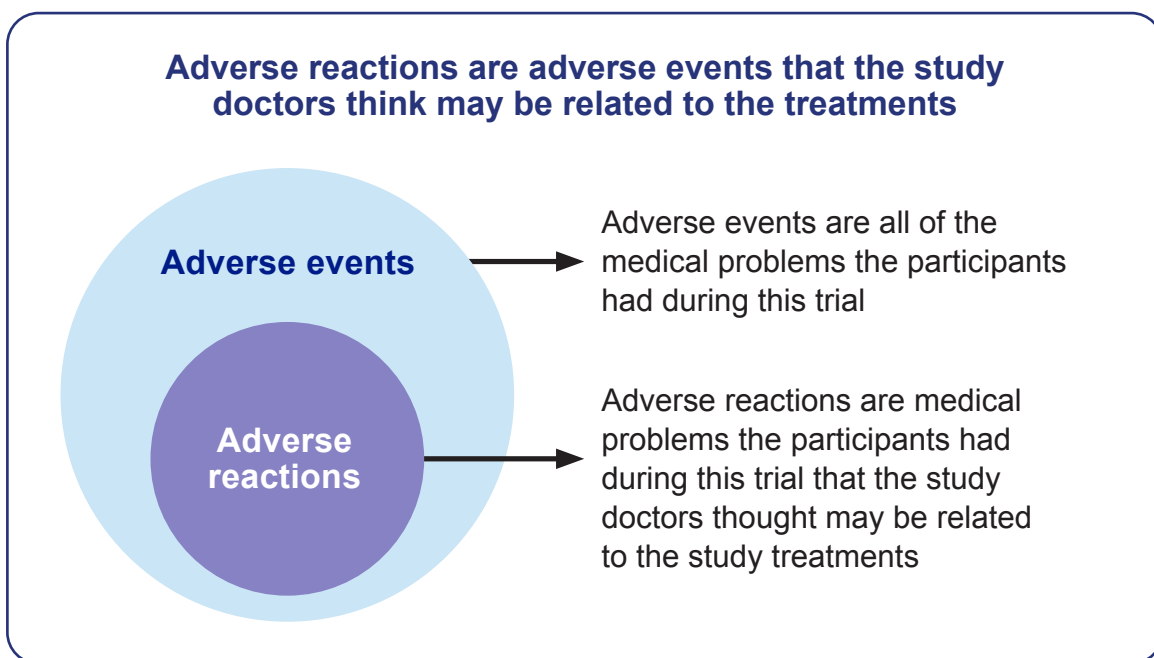
The adverse events that happened during the study occurred in 1 participant each. These were:

- Infusion site pain
- Joint pain
- Infusion site inflammation
- Infusion site swelling
- Toothache
- Gum disease
- Bruise

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.



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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?

None of the participants had serious adverse reactions.

How many participants had any adverse reactions?

There were 18.8% of participants who had adverse reactions. This was 3 out of 16 participants.

What adverse reactions did the participants have?

The adverse reactions that happened during the study occurred in 1 participant each. These were:

- Infusion site pain
- Infusion site inflammation
- Infusion site swelling

How has this study helped patients and researchers?

The results of this study have helped researchers learn more about the safety of levetiracetam when given as an IV infusion 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 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.

At the time this study ended, further clinical studies in epilepsy with levetiracetam given as an IV infusion were planned.

Where can I learn more about this study?

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

- <http://www.clinicaltrials.gov/ct2/show/study/NCT01407523>

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

Study Information

Protocol Number: N01378

Study Sponsor: UCB Japan, Co., Ltd., sponsored this study. It is referred to as UCB in this summary.

Full Study Title: An open-label, multicenter study to evaluate the safety of adjunctive treatment with intravenous levetiracetam (L059IV) in epilepsy patients aged ≥ 16 years with partial onset seizures

National Clinical Study Number: NCT01407523

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
Bruise	Contusion
Gum disease	Gingivitis
Joint pain	Arthralgia



This summary was last updated on 22 December 2021.
The final clinical study report is dated 22 October 2012.