

Clinical Study Results

Study Sponsor: UCB Biopharma SPRL

Treatments Studied: Levetiracetam and carbamazepine

Protocol Number: N01364

Short Study Title: A study to learn if levetiracetam works when taken by itself in Chinese participants with newly diagnosed epilepsy who have focal seizures

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 a large number of 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 China as a treatment to be used by itself for people with epilepsy. In this study, the researchers asked for the help of Chinese people with epilepsy. They compared levetiracetam to an anti-seizure medicine called carbamazepine. When the study started, doctors often used carbamazepine as the first treatment for patients' seizures. Carbamazepine was also the medicine that many researchers chose to compare with other medicines for seizures.

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?

There were 433 male and female participants in mainland China who took study treatment in this study. They were 16 to 77 years old.

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

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

Each participant was in the study for up to about 8 months, but the whole study lasted about 2 years. The study started in September 2013 and ended in October 2015.

What treatments did the participants take?

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

The participants, study doctors, and UCB staff knew which treatment the participants were taking.





The researchers used a computer program to randomly choose if the participants took levetiracetam or carbamazepine. This helped make sure the treatments were chosen fairly and comparing the results of the treatments was as accurate as possible.

During this study:

- 218 participants took levetiracetam
- 215 participants took carbamazepine

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The chart below shows the treatments the researchers planned for this study:






 The participants took levetiracetam twice each day for up to 32 weeks.	 The participants took carbamazepine each day for up to 32 weeks.
 The dose of levetiracetam was 500 to 1,000 mg a day.	 The dose of carbamazepine was 200 to 400 mg a day. When taking 200 mg, the participants took it once a day. When taking 400 mg, the participants took 200 mg twice a 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 join the study. This part lasted up to about 1 week.



During the study:

 The participants kept track of their seizures every day using diaries.
 The participants visited the clinic up to 8 times.
 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.



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This study had 2 main parts:

Part 1 lasted 2 weeks. During this part, the participants took either:

-  500 mg of levetiracetam each day
-  200 mg of carbamazepine each day

Part 2 lasted 27 weeks. During this part, the participants took either:

-  1,000 mg of levetiracetam each day
-  400 mg of carbamazepine each day

After Part 2, some participants entered a program where they could continue taking their study treatment and the rest did not. The participants who entered the program joined it right away.

The participants who did not join the program took a lower dose of their study treatment for 1 week, and then stopped taking it. They had a clinic visit 2 weeks later, then left the study.

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 researchers included 357 of the 433 participants in the results shown below. They included only participants who joined Part 2 of the study and had provided seizure information in that part. The researchers did not include participants who had important changes from the study plan that might have affected the conclusions about the study results. The researchers decided what type of changes might affect their conclusions before they looked at the study results.

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

The researchers wanted to learn if the percentage of participants who had no seizures for 6 months in a row was similar or higher in the participants who took levetiracetam compared with the participants who took carbamazepine.

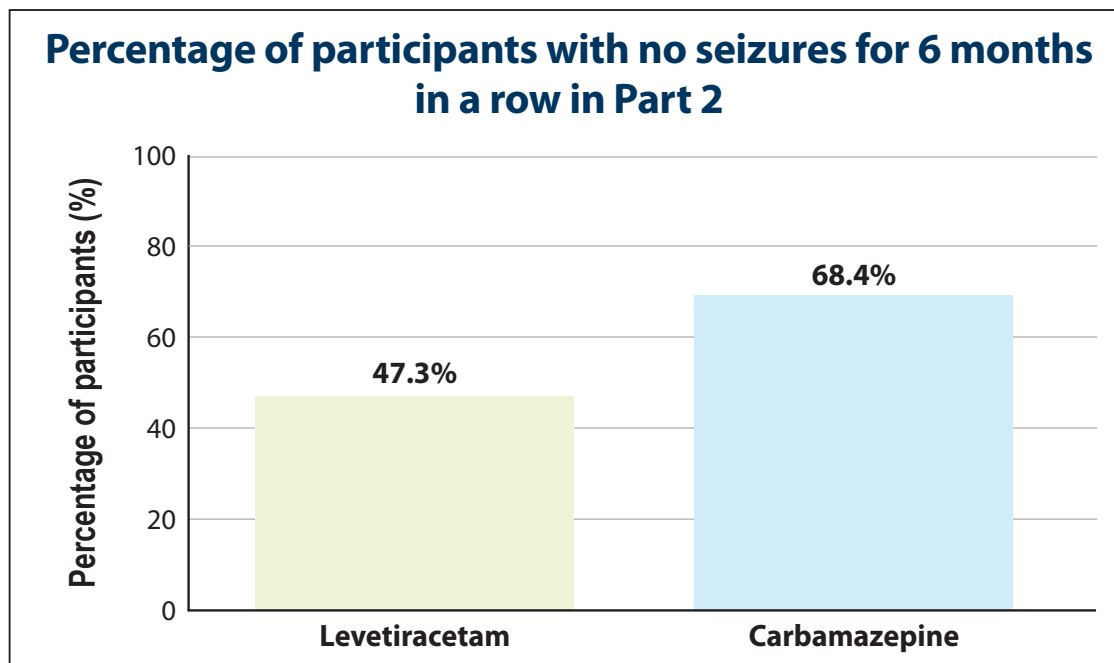
To find this percentage, the researchers asked the participants to record the number of seizures they had during Part 2 in their diaries. The researchers counted the number of participants with no seizures for 6 months in a row. Since the participants took a higher dose of study treatment in Part 2 than in Part 1, the researchers started counting the seizures after 1 week had passed in Part 2. This was done so the participants could adjust to taking a higher dose.

The researchers used mathematical methods to look at these results. Using these methods, they could not conclude that levetiracetam helped control the participants' seizures about the same as or more than carbamazepine did.

The researchers found that:

- 47.3% of the participants who took levetiracetam had no seizures for 6 months in a row. This was 88 out of 186 participants.
- 68.4% of the participants who took carbamazepine had no seizures for 6 months in a row. This was 117 out of 171 participants.

The graph below shows the 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 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 the study, serious adverse reactions happened in:

- None of the participants who took levetiracetam. This was 0 out of 218 participants.
- 1.9% of the participants who took carbamazepine. This was 4 out of 215 participants.

None of the participants died due to serious adverse reactions.

What serious adverse reactions did the participants have?

The serious adverse reactions are listed below. All the participants who had serious adverse reactions were taking carbamazepine. None of the participants who took levetiracetam had serious adverse reactions.

- Memory loss. This happened in 1 participant.
- Rash. This happened in 1 participant.
- Rash due to drug. This happened in 1 participant.
- Spots on the body caused by too few platelets in the blood. This happened in 1 participant.

How many participants had any adverse reactions?

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

- 28.0% of the participants who took levetiracetam. This was 61 out of 218 participants.
- 37.2% of the participants who took carbamazepine. This was 80 out of 215 participants.

What adverse reactions did the participants have?

In this study, the most common adverse reactions in the participants taking levetiracetam were dizziness and sleepiness. Dizziness was the most common adverse reaction in participants taking carbamazepine.

The table below shows the adverse reactions that happened in 5% or more participants in either of the treatment groups. This means they happened in at least 1 out of every 20 participants. There were other adverse reactions, but these happened in fewer participants.

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

	Levetiracetam (out of 218 participants)	Carbamazepine (out of 215 participants)
Dizziness	9.6% (21)	6.0% (13)
<u>Sleepiness</u>	9.2% (20)	2.8% (6)

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/results/NCT01954121?term=NCT01954121&rank=1>

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

Study Information

Protocol Number: N01364

Study Sponsor: UCB Pharma SA sponsored this study. It is now called UCB Biopharma SPRL and referred to as UCB in this summary.

Full Study Title: A multicenter, open-label, randomized, parallel-group, active controlled study comparing the efficacy and safety of levetiracetam to carbamazepine used as monotherapy in subjects (≥ 16 years) newly or recently diagnosed as suffering from epilepsy and experiencing partial seizures

National Clinical Study Number: NCT01954121

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

Memory loss:	Also called “memory impairment.”
Rash due to drug:	A certain kind of rash that looks like it is caused by a drug. Also called “drug eruption.”
Sleepiness:	Also called “somnolence.”
Spots on the body caused by too few platelets in the blood:	Having small purple or red spots on the body caused by a low number of platelets in the blood. Platelets are needed for blood to clot. Also called “thrombocytopenic purpura.”



This summary was last updated on 04 September 2019.
The final clinical study report is dated 10 February 2016.