Clinical Trial Results

Research Sponsor: Eisai Ltd.

Drug Studied: Perampanel, also called Fycompa® or E2007

Short Trial Title: A trial to learn how perampanel works and how safe it is when taken without other treatments by people with untreated epilepsy and partial-onset seizures

Thank you!

You and your caregiver took part in this clinical trial for the trial drug perampanel, also called E2007. You, your caregiver, and all of the participants helped researchers learn more about perampanel, which may help people with untreated epilepsy and partial-onset seizures.

Eisai, a Japanese pharmaceutical company and the sponsor of this trial, thanks you for your help. Eisai is committed to improving health through continuing research in areas of unmet need and sharing with you the results of the trial you and your caregiver participated in.

Eisai prepared this summary with a medical and regulatory writing organization called Certara Synchrogenix.

If you and your caregiver participated in the trial and have questions about the results, please speak with the trial doctor or staff at your trial site.

What is this summary about?

This is a summary that shows the overall results of the trial. Individual results for each person who took part are not shown in this summary and might be different from the overall results.

A full list of the questions researchers wanted to answer can be found on the websites listed at the end of this summary. When a scientific report of this clinical trial is available, it can be found on the websites listed at the end of this summary.

Researchers look at the results of many trials to decide which treatment options may work best and are well tolerated. Other trials may provide new information or different results. Always talk to a doctor before making any treatment decisions.

What is epilepsy?

Epilepsy affects the brain. It is a nervous system disorder in which brain activity becomes abnormal. This can cause seizures and loss of awareness and consciousness. As the epilepsy gets worse, so will the symptoms.

A partial-onset seizure is the most frequent type of seizure. It starts in a specific part of the brain that may or may not be linked to a loss of awareness or consciousness.

A secondary generalized seizure is a seizure that spreads from one specific part of the brain to the whole brain.

What has happened since the trial started?

The trial started in June 2017 and ended in July 2020.

The sponsor of the trial reviewed the data collected and created a report of the results. This is a summary of that report.

The trial included 98 screened participants from 38 trial sites in Japan and Korea.

Of the 98 screened participants in this trial, 89 participants took at least 1 dose of trial drug.

Why was the research needed?

Clinical trials answer many important questions. In this trial, researchers wanted to learn how well perampanel works and how safe it is when taken without other treatments by people with untreated partial-onset seizures.

Perampanel tablets have already been approved in combination with other treatments for the treatment of people with partial-onset seizures in the European Union, the United States, Japan, and 50 other countries. However, treating partial-onset seizures with a single treatment is recommended. The researchers wanted to see if perampanel, when taken without other antiseizure medications, could help the participants with untreated partial-onset seizures to get control of their seizures.

The researchers in this trial also wanted to find out if participants had any adverse events during the trial. An adverse event is a medical problem that may or may not be caused by the trial drug.

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

- How many participants were seizure-free after 26 weeks of treatment with perampanel 4 mg once a day?
- How many participants were seizure-free after 26 weeks of treatment with perampanel 4 mg to 8 mg once a day?
- What adverse events did participants taking perampanel have?

It is important to know that this trial was designed to get the most accurate answers to the questions listed above. There were other questions that the researchers wanted to answer to learn more about how perampanel works. But, these were not the main questions the trial was designed to answer.

What kind of trial was this?

To learn more about how perampanel works and how safe it is, the researchers asked for the help of people like you. The participants in the trial were 15 to 72 years old.

All of the participants in this trial had untreated partial-onset seizures with or without secondary generalized seizures.

This trial was "open-label". This means that the participants, caregivers, trial doctors and staff, and the sponsor knew which trial drug the participants took.

The trial had 3 phases called the pretreatment phase, the treatment phase, and the extension phase.

During the pretreatment phase, participants were checked to see if they could participate in the trial. They also asked participants or their caregivers to complete the questionnaire and the diary for seizure counts and types.

During the treatment phase, participants started taking the trial drug. The treatment phase consisted of the 4-mg treatment phase and, if participants required a higher dose, the 8-mg treatment phase.

- During the 4-mg treatment phase, participants began taking 1 tablet of 2 milligrams (also called mg) perampanel once a day for 2 weeks. After that, the 2 mg was then increased by 2 mg to get to a daily dose of 4 mg (2 tablets of 2 mg perampanel each) once a day for 4 weeks. This is called the 4-mg titration period.

  During the 26-week maintenance period, participants continued taking perampanel 4 mg once a day.

- During the 8-mg treatment phase, participants began taking 3 tablets of 2 mg perampanel (that is, 6 mg total) for 2 weeks. After that, the 6 mg dose was increased by 2 mg to get to a daily dose of 8 mg (4 tablets of 2 mg perampanel) for 2 weeks. This is called the 8-mg titration period.

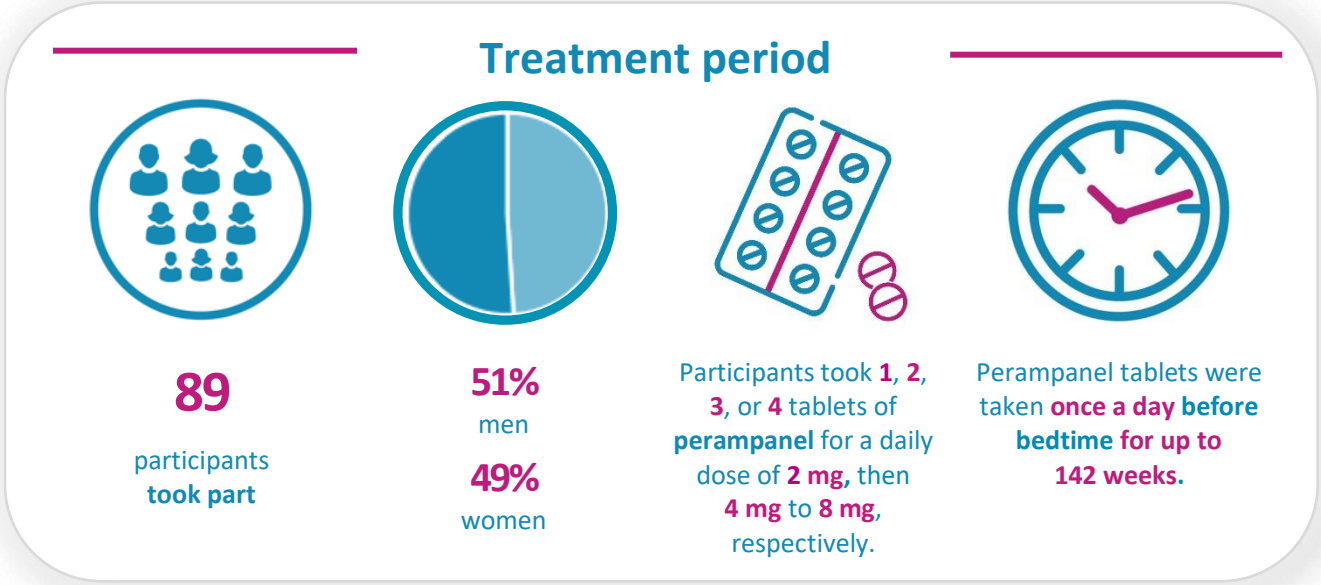
  During the 26-week maintenance period, participants continued taking perampanel 8 mg once a day.

Participants who completed the treatment phase of this trial could continue taking perampanel in the extension phase of this trial, with the dose that they last took in the maintenance period (4 mg or 8 mg). The extension phase lasted up to 3 months after perampanel was approved in each country.

The trial drug was taken as a tablet by mouth, once a day before bedtime.

How did participants receive the treatment?

The figure below shows how treatment was given in this trial.



What happened during the trial?

The figure below shows what happened during the treatment and extension phases of the trial.

Treatment phase

Throughout the treatment phase (up to 62 weeks), the trial doctors or staff:

- Checked the participants' health, heart health, asked what medications they were taking, and took blood or urine samples.
- Asked participants how they were feeling and if they had any adverse events.
- Asked participants or their caregivers to continue completing the questionnaire.
- Asked participants or their caregivers to continue completing the diary and to return it at each visit.

Extension phase

Some participants who completed the treatment phase entered the extension phase of the trial.

All participants or their caregivers continued to complete the diary.

The trial doctors or staff continued to check the participants' health, heart health, asked what medications they were taking, and took blood or urine samples.

Asked participants or their caregivers to continue completing the questionnaire.

If a participant was withdrawn or completed the trial, then he or she returned to the trial site about 4 weeks after taking the last dose of treatment for their final visit and tests.

If a participant withdrew from the study, then they returned their diary at the early discontinuation visit.

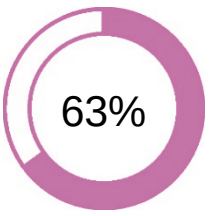
What were the results of the trial?

Among the 89 participants who took the trial drug, 73 participants entered the 4-mg maintenance period and had completed at least 1 seizure diary.

How many participants were seizure-free after 26 weeks of treatment with perampanel 4 mg once a day?

To answer this question, the participants or their caregivers were given diaries to record how often and what kind of seizures they had during the trial. To see how many participants were seizure-free, the researchers checked the diaries to see whether the participants experienced seizures during the treatment phase of 26 weeks.

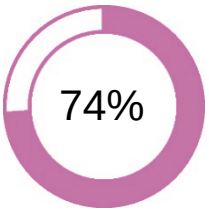
The chart below shows the average number (percentage) of participants who were seizure-free.



Overall, 46 out of 73 participants (63%) were seizure-free after 26 weeks of treatment with perampanel 4 mg once a day.

How many participants were seizure-free after 26 weeks of treatment with perampanel 4 mg to 8 mg once a day?

The chart below shows the percentage of participants who were seizure-free.



Overall, 54 out of 73 participants (74%) were seizure-free after 26 weeks of treatment with perampanel 4 mg to 8 mg once a day.

What medical problems did participants have?

Medical problems that happen in clinical trials are called “adverse events”. An adverse event is called “serious” when it is life threatening, causes lasting problems, or the participant needs to be admitted to a hospital.

This section is a summary of the adverse events that happened during this trial. These medical problems may or may not be caused by the trial drug. The websites listed at the end of this summary may have more information about the medical problems that happened in this trial. A lot of research is needed to know whether a drug causes a medical problem.

The results of all 89 participants who took at least 1 dose of trial drug are included below. All participants were checked by trial doctors for medical problems at least once.

How many participants had adverse events?

In this trial, 74 out of 89 participants (83%) had adverse events.

The table below shows how many participants had adverse events in this trial.

Adverse Events in This Trial

	Perampanel (89 participants)
How many participants had adverse events?	74 (83%)
How many participants had serious adverse events?	13 (15%)
How many participants stopped taking the trial drug because of adverse events?	9 (10%)

% is the percentage of participants with an adverse event.

What were the most common serious adverse events?

An adverse event is called “serious” when it is life threatening, causes lasting problems, or the participant needs to be admitted to a hospital.

In this trial, 13 out of 89 participants (15%) had serious adverse events.

The table below shows the serious adverse events that happened in 2% or more of participants. There were other serious adverse events, but these happened in fewer participants.

Most Common Serious Adverse Events in This Trial

	Perampanel (89 participants)
Break of the humerus bone in the upper arm (humerus fracture)	2 (2%)
Epilepsy	2 (2%)

% is the percentage of participants with the adverse event.

In this trial, none of the participants died due to serious adverse events.

What were the most common adverse events?

In this trial, 74 out of 89 participants (83%) had adverse events while on treatment.

The table below shows the adverse events that happened in 5% or more of participants. There were other adverse events, but these happened in fewer participants.

Most Common Adverse Events in This Trial

	Perampanel (89 participants)
Dizziness	34 (38%)
infection of the nose and throat (cold)	19 (21%)
Headache	13 (15%)
Feeling sleepy	12 (14%)
Epilepsy	6 (7%)

% is the percentage of participants with the adverse event.

How has this trial helped patients and researchers?

In this trial, researchers learned more about whether perampanel may have helped people with untreated partial-onset seizures when they take 4mg to 8 mg of perampanel once a day.

Researchers look at the results of many trials to decide which treatment options may work best and are well tolerated. This summary shows only the main results from this one trial. Other trials may provide new information or different results.

Further clinical trials with perampanel are not planned.

Where can I learn more about the trial?

You can find more information about this trial on the websites listed below. If a full report of the trial results is available, it can also be found here:

- http://www.clinicaltrialsregister.eu - Once you are on the website, click "**Home and Search**", then type **2019-003734-17** in the search box and click "**Search**".
- http://www.clinicaltrials.gov - Once you are on the website, type **NCT03201900** into the search box and click "**Search**".

Full trial title: A Multicenter, Uncontrolled, Open-label Study and Extension Study for Verification of Efficacy and Safety for Perampanel Monotherapy in Untreated Patients with Partial Onset Seizures (Including Secondary Generalized Seizures)

Protocol number: E2007-J000-342

Eisai, the sponsor of this trial, has headquarters in Tokyo, Japan, and regional headquarters in Woodcliff Lake, New Jersey, USA and Hatfield, Hertfordshire, UK. The phone number for general information is 44-845-676-1400.

Thank you

Eisai would like to thank you for your time and interest in participating in this clinical trial. Your participation has provided a valuable contribution to research and improvement in health care.

Eisai Co., Ltd. is a global research and development-based pharmaceutical company headquartered in Japan. We define our corporate mission as “giving first thought to patients and their families and to increasing the benefits health care provides,” which we call our human health care (hhc) philosophy. With over 10,000 employees working across our global network of R&D facilities, manufacturing sites, and marketing subsidiaries, we strive to realize our hhc philosophy by delivering innovative products in multiple therapeutic areas with high unmet medical needs, including Oncology and Neurology. For more information, please visit http://www.eisai.com.

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