Clinical Study Protocol Synopsis

A safety and efficacy study of perampanel as an add-on treatment in pediatric participants with epilepsy

Full Study Title:	An Open-Label Study with Extension Phase to Evaluate the Efficacy and Safety of Perampanel Administered as an Adjunctive Therapy in Pediatric Subjects (Age 1 Month to Less Than 18 Years) With Childhood Epilepsy		
EU Clinical Study Number:	2018-004456-38	**US Clinical Study Number:**	NCT04015141
Study Sponsor:	Eisai, Inc., Nutley, NJ, USA	**Telephone Number:**	+1 201-692-1100

Why is this research needed?

Researchers are looking for a different way to treat children and adolescents with epilepsy. **Epilepsy** is a brain disorder that causes recurring seizures. Current treatments for epilepsy include medicines that can help control seizures. **Perampanel** may be able to help children and adolescents with epilepsy by reducing glutamate in the brain. Glutamate is a chemical that nerve cells use to communicate with each other. Too much glutamate in the brain may be involved in causing seizures.

In this study, researchers want to find out how well perampanel may work and understand its safety as an add-on treatment in children and adolescents with epilepsy.

What treatment is being studied?

This study has 3 parts:

- **Core Study:** This part consists of a period where study doctors check participants' health to make sure they can join the study and a period where participants take perampanel for 23 weeks.
- **Extension A:** Once participants complete the Core Study, participants may join this part where they can continue taking perampanel.
- **Extension B:** Similar to Extension A, participants may join this part if perampanel is not commercially available in their country.

All participants will take perampanel as a tablet or as a suspension (a liquid with solid particles in it).

Doses of perampanel will be measured in milligrams for tablet or milligrams per milliliter for suspension.

Everyone involved in the study will know that participants will take perampanel. This is called an open-label study.

What are the goals of this study?

The primary objective is to investigate how well perampanel may work in reducing the frequency of seizures after 23 weeks of treatment in the Core Study.

The secondary objectives are to investigate in more detail how well perampanel may work in treating seizures and epilepsy in the Core and Extension parts of the study. Researchers will also investigate the safety of perampanel and its movement within the body.

What are the measurements in this study?

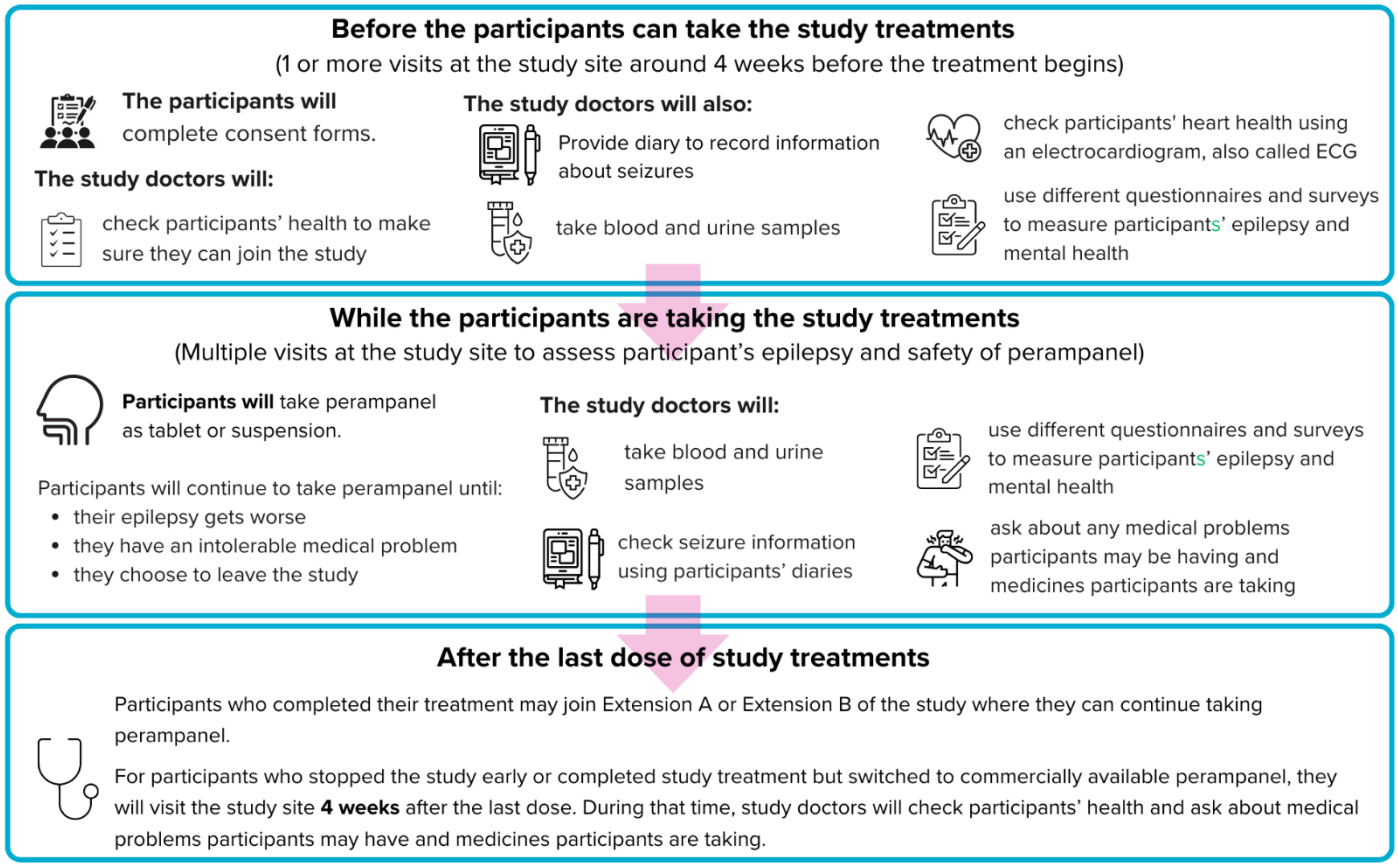
1. **Main measurement:** To investigate the primary objective, researchers will check the number of seizures participants have during the Core Study.
2. **Secondary measurements:** To investigate the secondary objectives, researchers will use other questionnaires and surveys to measure how severe a participant's epilepsy is. They will also collect information on any medical problems that participants may have.

The researchers will also collect other information about perampanel. But the measurements described above are the most important for this study.

What will happen during the study?

Before participants take part in the study, study doctors will explain the study to participants and answer any questions they may have.

The chart below shows what will happen in the Core Study.



Who can and cannot take part in this study?

People can take part in this study if they:

- Are 1 month to less than 18 years
- Are diagnosed with epilepsy
- Are taking epilepsy medications

People cannot take part in this study if they:

- Have seizures lasting more than 5 minutes and requiring a hospital visit
- Have other conditions that according to the study doctors may prevent them from participating

These are just some of the main guidelines. Study doctors will check all guidelines to see if a person can join this study. Participation in this study is voluntary. Participants can leave the study at any time.

What are the potential benefits and risks of taking part in this study?

Potential Benefits (Advantages): Perampanel may help to treat the participant's epilepsy. The information collected in this study may help doctors learn more about perampanel, which could help other people with epilepsy.

Potential Risks (Disadvantages): Perampanel may not help to treat the participant's epilepsy, or they might have side effects from perampanel. There may be additional risks, which are unknown and unexpected.