

A study to learn how well E2511 may work, its safety profile, and how the bodies of adult participants with early Alzheimer's disease handle it

Full Study Title:	A Proof-of-Mechanism, Open-Label, Parallel Group Study With an Open-Label Extension Phase to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of E2511 in Subjects With Early Alzheimer's Disease		
EU Clinical Study Number:	N/A	US Clinical Study Number:	NCT07768592
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 people who have early Alzheimer's disease. **Alzheimer's disease** (or **AD**) is a brain disorder that causes problems with memory, thinking, and behavior. Current treatments for AD include medicines that can help reduce some of its symptoms, but not prevent the disease from getting worse.

E2511 may be able to help people with early AD by increasing a chemical in the brain called acetylcholine (ACh). **ACh** helps nerve cells in the brain to communicate and supports memory and thinking.

In this study, researchers want to learn about how well E2511 may work, its risks and safety, and how the bodies of participants handle it. This 2-part study has a Core study and then an Extension phase.

What treatment is being studied?



Participants will take either **E2511** or **donepezil** tablets once daily.



Donepezil is a medicine that is used to treat memory and behavioral problems because of AD.



Participants will take **E2511** (Part A or Part B) or **donepezil** (Part A) for 14 days in Core study and for 540 days (about 1 and a half years) in Extension phase.



All people involved in the study will know which treatment the participants will take. This is called an **open-label** study.

What are the goals of this study?

Core Study	The primary objective is to investigate whether E2511 can affect the ACh level in the brain. The secondary objectives are to check if participants can safely take E2511 and to learn how the participants' bodies handle E2511.
Extension Phase	The primary objective is to check if participants can safely take E2511 for a long time. The secondary objective is to investigate whether E2511 can affect ACh levels in the brain over a long period of time.

The Extension phase will only begin if the results from the Core study show that E2511 can increase the ACh level in the brain. If this is not shown, then the Extension phase will not proceed.

What are the measurements in this study?

Core Study	Main measurement: To investigate the primary objective, researchers will collect and analyze results from a brain scan each participant has after 14 days of treatment.
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Secondary measurements: To investigate the secondary objectives, researchers will check all safety information collected and will measure the level of E2511 in the blood.

Extension Phase

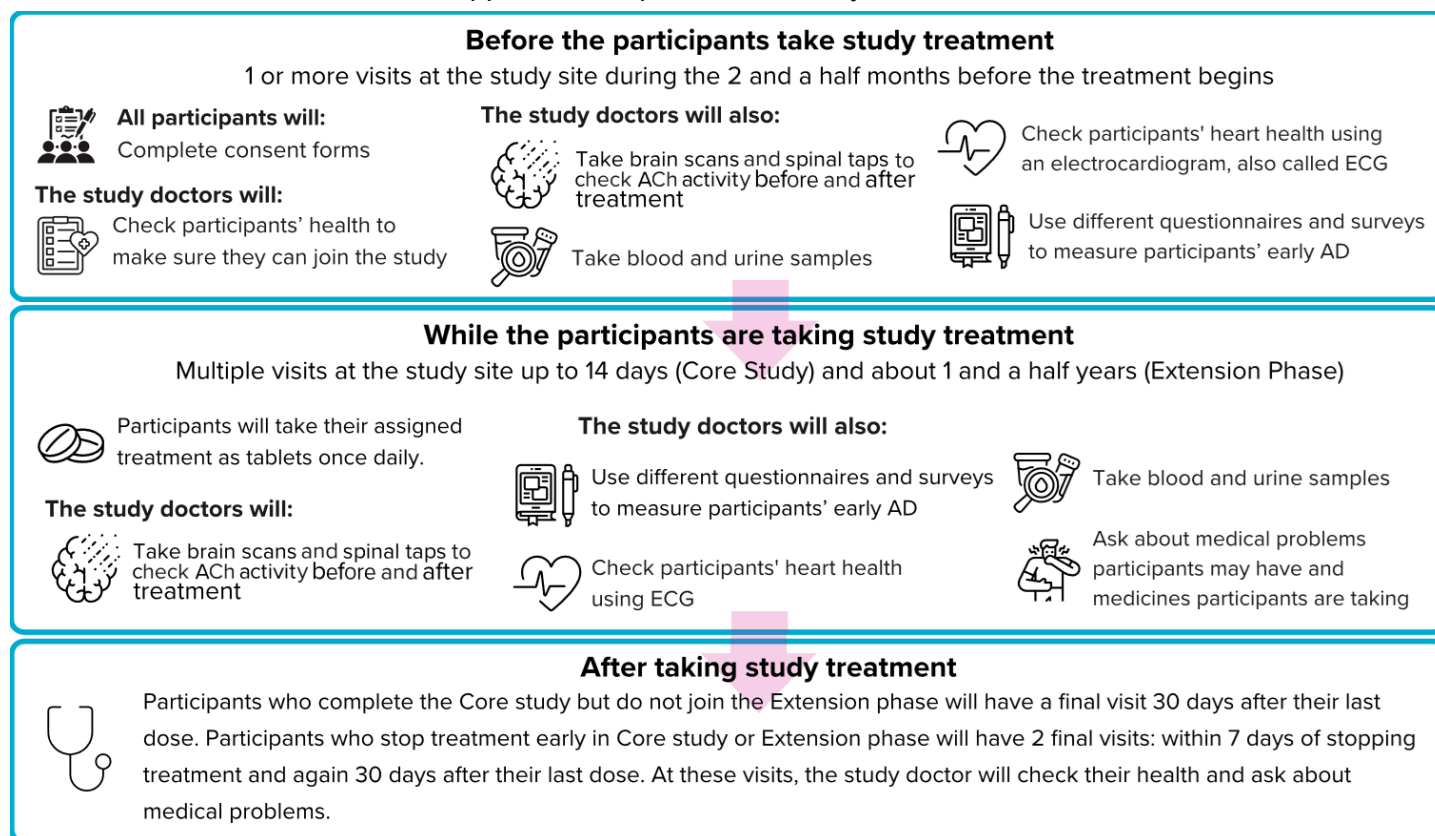
Main measurement: To investigate the primary objective, researchers will check all safety information collected.

Secondary measurements: To investigate the secondary objective, researchers will use the brain imaging scan results after 12 and 18 months of treatment.

The researchers will also collect other information about E2511, but the measurements described above are the most important for this study.

What will happen during the study?

The chart below shows what will happen in both parts of the study.



Who can and cannot take part in this study?



People can take part in this study if they:

- Are 50 to 85 years old
- Have memory and thinking problems caused by AD



People cannot take part in this study if they:

- Are pregnant or breastfeeding women
- Have certain medical conditions that require treatment

These are just some of the main study entry guidelines. Study doctors will check all of the study requirements 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): E2511 may help treat early AD. The information collected in this study may help doctors learn more about E2511 that could help people with early AD.

Potential Risks (Disadvantages): E2511 may not help to treat early AD, or participants might have a side effect from E2511 or donepezil. There may be additional risks that are unknown and unexpected.