

## A study to learn about the safety and tolerability of E2086 and how it moves in the body of healthy participants

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| <b>Full Study Title:</b>         | A Randomized, Double-Blind, Placebo-Controlled, Combined Multiple Ascending Dose Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Single Dose Study to Assess Food Effect of E2086 in Healthy Adult Subjects |                                   |
| <b>US Clinical Study Number:</b> | NCT06481488                                                                                                                                                                                                                                   |                                   |
| <b>Study Sponsor:</b>            | Eisai, Inc., Nutley, NJ, USA                                                                                                                                                                                                                  | Telephone number: +1 888-274-2378 |

### Why is this research needed?

Researchers are looking for a different way to treat people who have narcolepsy. Narcolepsy is a disorder associated with daytime sleepiness. Standard treatments for people with narcolepsy include medicines that help them stay awake and alert. E2086 may help treat people with narcolepsy by acting like the substance in the brain that helps control wakefulness.

This study has 2 parts:

- **In Part A:** Researchers want to compare blood and urine levels of E2086 in the bodies of Japanese and non-Japanese participants after participants have taken multiple doses of E2086 or placebo. During this part, no one involved in the study will know which treatment participants will take.
- **In Part B:** Researchers want to learn how food may affect levels of E2086 in the blood of participants. During this part, everyone involved in the study will know that participants are taking E2086.

### What treatment is being studied?



In **Part A**, participants will take E2086 or placebo tablets once daily during treatment period.



A **placebo** looks like E2086 but does not have any medicine in it.



In **Part B**, participants will take a single dose tablet of E2086 with food or without food during 2 separate treatment periods.

### What are the goals of this study?

The **primary objective** is to investigate the safety and tolerability of different doses of E2086.

The **secondary objectives** are to investigate the blood and urine levels of different doses of E2086 in Japanese and non-Japanese participants. Researchers will also investigate the effect of food on the levels of E2086 in the blood of participants after a single dose of E2086.

### What are the measurements in this study?

1

**Main measurement:** To investigate the primary objective, researchers will collect information on any medical problems that participants may have during the study. They will also collect participants' laboratory and physical examination results to check on the participants' health.

2

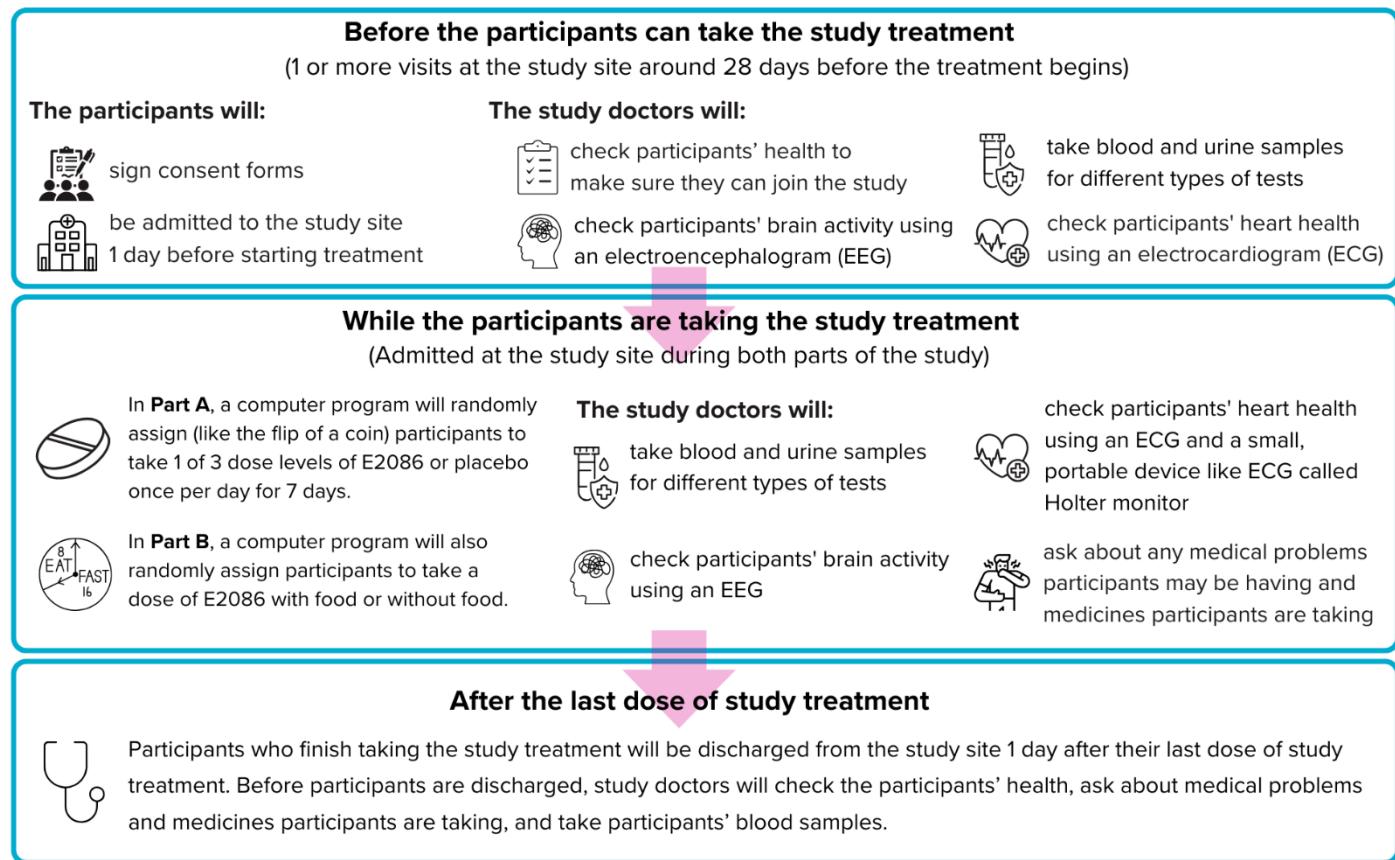
**Secondary measurements:** To investigate the secondary objectives, researchers will compare the levels of E2086 in the blood and urine of Japanese and non-Japanese participants in Part A. In Part B, they will also measure the levels of E2086 in the blood of participants when taken with food and without food.

The researchers will also collect other information about E2086, but the measurements described above are the most important for this study.

## What will happen during the study?

Before participants can 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 each part of the study.



## Who can and cannot take part in this study?

People can take part in this study if they:



- are between 18 and 55 years of age for non-Japanese participants
- are between 20 and 55 years of age for Japanese participants who have been living a Japanese lifestyle in the United States for no more than 5 years
- are non-smokers



People cannot take part in this study if they:

- are women who can become pregnant
- have any medical conditions that will require treatment

These are just some of the main study entry guidelines. Study doctors will check all of the 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):** The information collected in this study may help doctors learn more about E2086 that could help people with narcolepsy.

**Potential Risks (Disadvantages):** Participants might have side effects from E2086. Being part of a study can burden participants, such as making time for going to the study site and being admitted to the study site on scheduled days. There may be other risks that are unknown and unexpected.