

A study to learn how E2086 is broken down and removed from the body of healthy male participants

Full Study Title: An Open-Label, Single Dose Study to Determine the Metabolism and Excretion of [¹⁴C]E2086 in Healthy Male Subjects

US Clinical Study Number: NCT07308236

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 narcolepsy. Narcolepsy is a condition that makes it hard to stay awake during the day. 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 a substance in the brain that helps control wakefulness.

In this study, researchers want to learn about how E2086 is broken down in the body and removed from the body of healthy male participants.

What treatment is being studied?



Participants will take 1 dose of [¹⁴C]E2086 by mouth (oral) after not eating for at least 10 hours overnight.



[¹⁴C]E2086 is E2086 that is made with a small dose of radioactive label called carbon-14 (¹⁴C). The use of (¹⁴C) helps researchers track E2086 in the body.



Participants and researchers will know that all participants are taking [¹⁴C]E2086. This is called an "open-label" study.

What are the goals of this study?

The primary objective of this study is to investigate how E2086 is broken down in the body and removed from the body of healthy male participants.

The secondary objectives are to find out the chemical structure of the breakdown products (also called metabolites) of E2086 in the blood, urine, and stool and to learn about the safety of E2086.

What are the measurements in this study?

1

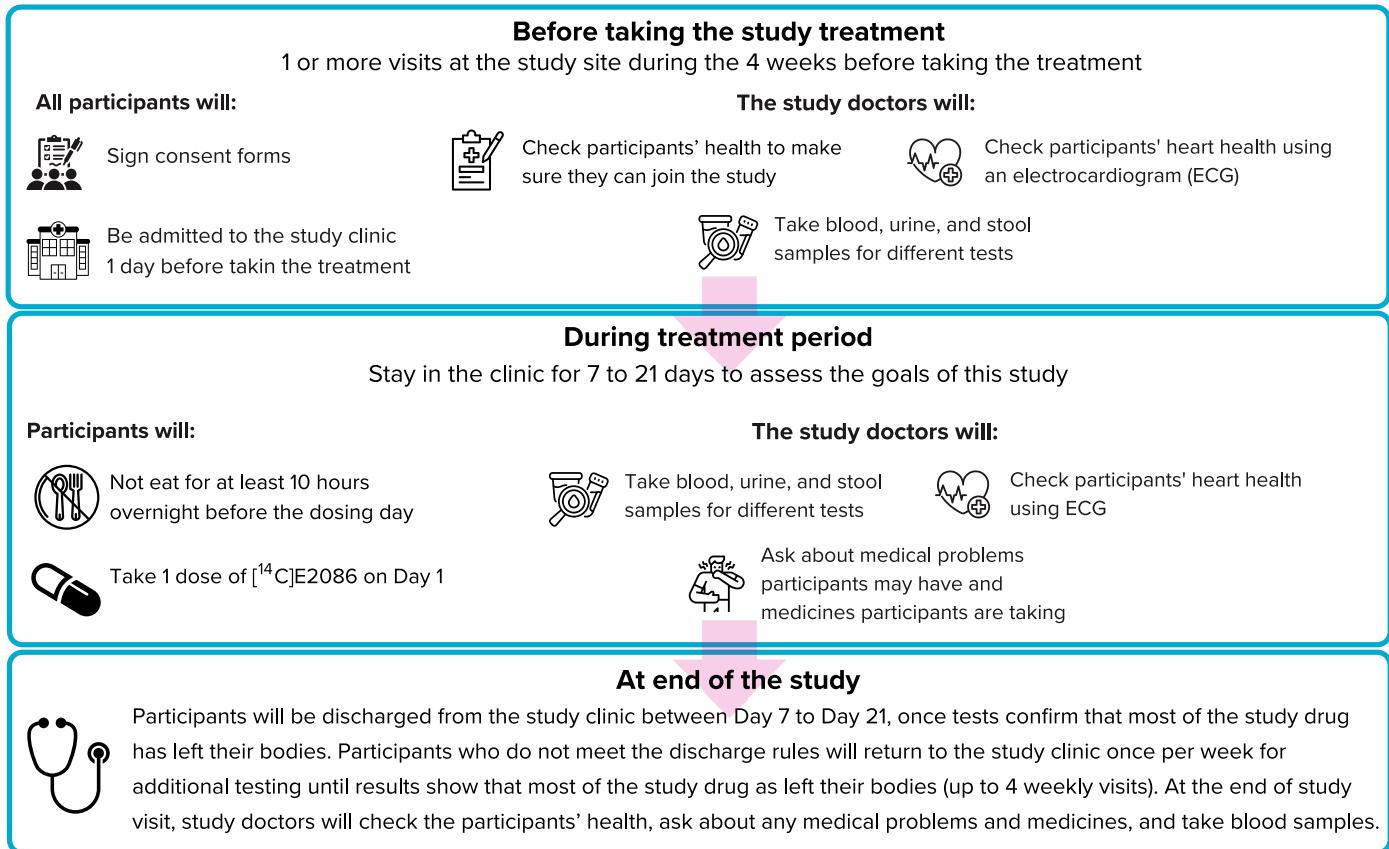
Main measurement: To investigate the primary objective, researchers will measure how much E2086 is in the blood and how much of E2086 and its metabolites leave the body through the urine and stool after participants take [¹⁴C]E2086.

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Secondary measurements: To investigate the secondary objectives, researchers will identify the metabolites of E2086 in the blood, urine, and stool after participants take [¹⁴C]E2086. Researchers will also check for any medical problems and/or unusual laboratory measurements, vital signs (like blood pressure), and other findings related to safety during the study.

What will happen during the study?

The chart below shows what will happen in the study.



Who can and cannot take part in this study?

People can take part in this study if they:



- are healthy males
- are at least 18 years old

People cannot take part in this study if they:



- have received more than 2 radiolabeled drug in other studies in the past 12 months
- are unable to follow the rules to avoid a pregnancy in their partners

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 may help people with narcolepsy.

Potential Risks (Disadvantages): Participants may have side effects from E2086. There may be additional risks that are unknown and unexpected.