

A study to learn about the safety risks and tolerability of E1018 and how it moves in the body of healthy adult participants

Full Study Title: A First-In-Human, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose Study to Assess the Safety, Tolerability, and Pharmacokinetics of Oral E1018 in Healthy Adult Subjects

US Clinical Study Number: NCT06854042

Study Sponsor: Eisai, Inc., Nutley, NJ, USA Telephone number: +1 888-274-2378

Why is this research needed?

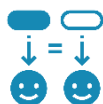
Researchers are looking for a new way to treat people who have malaria. **Malaria** is a disease caused by a parasite. This parasite is spread to people through bites of infected mosquitoes. Standard treatments for people with malaria include medicines that kill the parasite. **E1018** may help treat people with malaria by killing the parasite responsible for malaria.

In this study, researchers are trying to find out the safety risks and tolerability of a single dose of E1018 and how it moves in the body of healthy adult participants.

What treatment is being studied?



Participants will take a single dose of **E1018** or placebo.



A **placebo** looks like E1018 but does not have any medicine in it.



No one involved in the study will know which treatment participants will receive. This is called a **double-blind** study.

What are the goals of this study?

The primary objectives are to investigate the safety risks and tolerability of E1018 after a single dose at different dose levels in healthy adult participants and how E1018 moves in the body.

What are the measurements in this study?

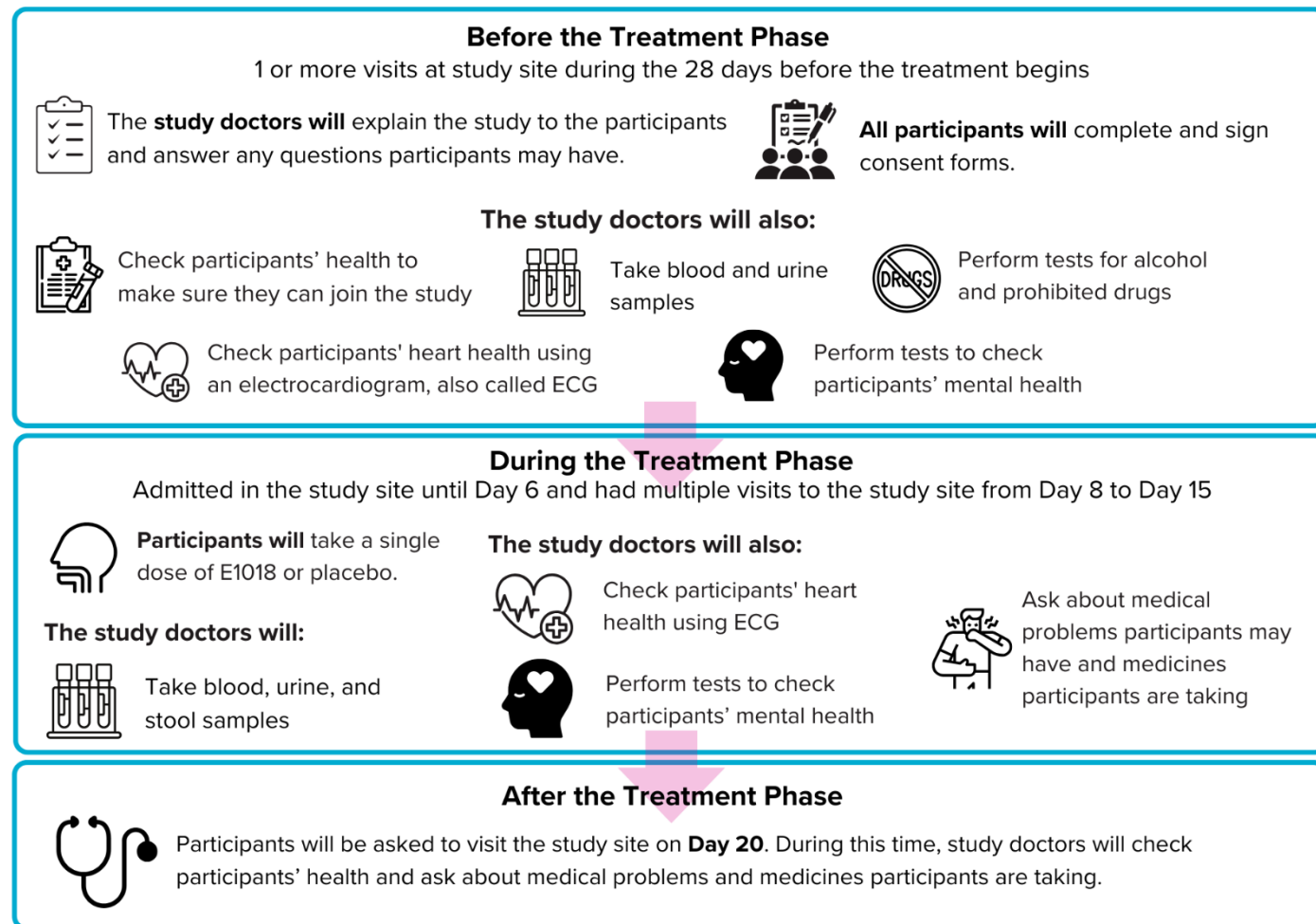
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Main measurement: To investigate the primary objectives, researchers will collect information on any medical problems participants may have during the study. They will also collect blood and urine samples to check how much of E1018 is in the blood and how much of E1018 is removed from the body through urine.

The researchers will also collect other information about E1018, 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 the study.



Who can and cannot take part in this study?



People can take part in this study if they:

- are 18 to 55 years of age
- are non-smokers or non-vapers



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): E1018 is being developed for the treatment of malaria. The information collected in this study may help doctors learn more about E1018, which could help people with malaria.

Potential Risks (Disadvantages): Participants might have side effects from E1018 or placebo. There may be other risks that are unknown and unexpected.