What is a Clinical Research Study?

A clinical research study is a carefully designed scientific evaluation of an investigational vaccine, medication, or treatment. Clinical research studies are conducted by doctors and researchers.

Why is Diversity Important in Clinical Research Studies?

Research has shown that certain diseases, treatments, and medications may impact people differently based on their age, gender, and genetic background, including race and ethnicity.

It is important to conduct research studies with diverse populations to help ensure that vaccines and medications are generally safe and effective (or that the benefits outweigh the risks).

Why is Clinical Research Important?

Clinical research helps doctors and scientists determine if an investigational vaccine, medicine, or therapy is safe and/or effective for use in humans to potentially treat or prevent a condition, disease, or disorder. Clinical studies often require a large number of volunteers to participate in a single study; sometimes thousands are needed to obtain reliable information.

The image depicted contains models and is being used for illustrative purposes only.

E.mbrace STUDY

Your participation in this study is an important step toward potentially finding a safe and effective vaccine to prevent blood infections caused by *E. coli* in the future.

Can I change my mind?

Yes. You can quit the study at any time, for any reason. Even if you begin the study, you can change your mind at any point.

Our study staff are ready to talk with you.

To learn more about this clinical research study and your eligibility, please contact the site at:

www.EmbraceVaccineStudy.com

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E.mbrace STUDY

Participate in a Clinical Study to Evaluate an Investigational Vaccine to Prevent Blood Infections

Help us find a safe and effective vaccine to prevent blood infections caused by *E. coli* in adults 60 years and older.

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What is Informed Consent?

Informed consent is a process of information exchange before an adult agrees to participate in research. Potential research participants will be asked to read and sign an Informed Consent Form, but will also be given instructions, verbally and in writing, question/answer sessions and other reading materials to assure the potential study participants' understanding and willingness to voluntarily enroll in the research.

So, before you agree to volunteer for the study, the study doctor or staff is required to explain all the details of the study, which will include the potential risks and benefits, and address your questions. After all of your questions have been answered, and if you wish to participate, you will sign a document called the Informed Consent Form to ensure:

- You agree to volunteer.
- You understand the study, including the study procedures, risks, and potential side effects of the study vaccine or medication.
- You understand that you can leave the study at any time, for any reason.

If you don't understand what is expected of you or the document, you should continue to ask questions and talk with the study doctor, your family, or others that you trust until you feel you understand.

What is a Vaccine?

A vaccine is a type of medicine that may help prevent or lessen the severity of certain diseases by causing the human body to form a defensive response against the disease. This defensive response is called the immune response, which is your body's way of fighting infections. An investigational vaccine is a vaccine that is only able to be used in clinical research studies like this one and is not available for use in the general public.

What is the Purpose of the E.mbrace Study?

The purpose of the E.mbrace Study is to assess the efficacy and safety of an investigational vaccine in the prevention of a blood infection caused by *E. coli* bacteria. Blood infections can lead to serious complications, such as dangerously low blood pressure and shock. Currently, there is no approved vaccine to prevent blood infections caused by *E. coli* bacteria.

Am I Eligible for the E.mbrace Study?

You may be able to participate in this study if you:

- Are 60 years of age or older.
- Have had a UTI in the past 2 years.

Additional eligibility criteria will be assessed by the study doctor prior to being enrolled. Not all individuals may qualify to participate in the research.

What is my Commitment as a Participant?

If eligible, you will be in the study for approximately 3 years. You will complete a minimum of 8 study visits, some in person and some remotely via telephone. Study staff will assist you with any concerns you may have about this minimal commitment.

What Can I Expect if I Join the Study?

If you qualify, choose to join the study, and sign the Informed Consent Form, you will be asked to attend a screening visit with the study doctor. At this visit, you will undergo tests and procedures to determine if you are a good match for being in the study.

You will be randomly assigned to one of the two study groups. This means you may receive either a placebo (contains no active vaccine) or the investigational vaccine. Neither you nor the study doctor will know which study group you are in.

The investigational vaccine or placebo will be given via a single injection on Day 1 of the study.

Only participants eligible for the study will receive study-required medical care at no cost. This does not include medical care to support daily health routines.

What if I'm Afraid of Needles?

We know that needles can create mixed emotions—fear and anxiety, to name a few! The investigational vaccine and placebo only take a few seconds to administer, similar to the routine vaccines you've had at your doctor's office. Let the study staff know your concerns about needles. They will help find a solution that works for you.

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