

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.

The Importance of Diversity 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 the benefits outweigh the risks).

Why is Clinical Research Important?

Clinical research helps doctors and scientists determine if an investigational vaccine, medicine or therapies are 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.



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.

See if you may be eligible to participate.

If you or someone you love is interested in participating in the E.mbrace clinical trial, please contact us at:

833-317-0662

Or visit:

www.EmbraceVaccineStudy.com



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Evaluating an Investigational Vaccine through Clinical Research

A clinical research study to evaluate an investigational vaccine in adults 60 years of age or older is now enrolling.



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With select Kroger locations now serving as primary clinical trial sites, getting involved could be as easy as stopping by your neighborhood pharmacy or The Little Clinic LLC.

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, then 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, and it is your body's way to fight 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.

Purpose of the E.mbrace Study

The purpose of this clinical research study is to assess the efficacy and safety of an investigational vaccine in the prevention of a blood infection caused by *E. coli* bacteria. Currently there is no approved vaccine to prevent blood infections caused by *E. coli* bacteria.

Am I Eligible?

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
- Feel comfortable, or have a caregiver who is comfortable, using a web-based program on a computer or tablet, or an application on a smartphone

Additional eligibility criteria will be assessed by the study team during the screening process prior to being enrolled in the study and receiving any investigational vaccine. Not all individuals may qualify to participate in the research.

About the E.mbrace Study

We are doing a clinical research study, called the E.mbrace Study, to see if an investigational vaccine can help protect adults, 60 years of age and older, against these blood infections. These blood infections can lead to serious complications such as dangerously low blood pressure or shock.

What we learn in this study may be helpful for infection prevention of these types of serious infections in the future.¹ These infections are more common in older people who have had urinary tract infections.

What Can I Expect if I Join the Study?

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

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 remote via telephone.

You will be randomly assigned to one of the two study groups. This means you may receive either a placebo (contains no active medicine) or the investigational vaccine. Neither you nor the study team 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.

Qualified participants may receive the investigational vaccine or placebo and some study-required medical care at no cost. The study will not pay for other medical care or current medication(s) needed to support your daily health care routine.

¹<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4871665/>

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