

RECRUITMENT E-MAIL FOR COHORT D  
ED\_CHIMERA01 ID Study  
21 June 2012

**Title: A Phase 1 Dose Escalating Study of two enterotoxigenic *Escherichia coli* Prototype adhesin-based vaccines with or without Modified Heat-labile Enterotoxin by Intradermal or Transcutaneous Immunization**

**What is this study about?**

In this study, we are testing a **vaccine against Enterotoxigenic *Escherichia coli* (ETEC), a bacterium that causes traveler's diarrhea. The vaccine is given by an injection ("a shot") under the skin of your arm or as a patch on top of the skin.** This vaccine is called CfaE and it is an **investigational vaccine**. This means that it is still being tested and is not approved for sale in the United States by the U.S. Food and Drug Administration.

The vaccine has two parts: CfaE, and mLT. This vaccine and its components has been given to humans either alone or in combination and given by a shot with a very small needle under the skin (intradermal, or ID, vaccination). The vaccine consists of a part of the bacteria that has been modified and may help prevent disease. The mLT is an adjuvant, which is to help increase the body's immune response (ability to resist infection or disease).

Our main goals are:

- 1) to test safety of the vaccine and your body's response to this vaccine; and
- 2) to study the body's responses to the vaccine.

**What is ETEC?**

One of the most common causes of enteric diseases are bacteria called *Escherichia coli* (*E. coli*), which occur after eating or drinking contaminated food or water. This is commonly associated with traveler's diarrhea. The military is involved in developing a vaccine because soldiers are frequently sent to areas where they may be exposed to *E. coli*. In turn, once vaccines are approved, they could be used by any traveler or person living in areas with these types of bacteria.

**What is required to participate in the study?**

Healthy adults between the **ages of 18 and 49** are asked to participate in this study. You will be scheduled for a **screening visit** and if you qualify and agree to participate in the vaccination, you will be scheduled for the first of three vaccinations in a six week period. Six-months later we will contact you by phone for a brief follow-up on your status. The study will last about 6 months, not including screening. Six-months later we will contact you by phone for a brief follow-up on your status. The study will last about 6 months, not including screening.

**In order to qualify:**

You must meet all of the eligibility criteria shown below:

- Healthy, between 18-45 years old, sign this informed consent document
  - Pass a written Test of Understanding and comprehension (>70% correct)
  - Able to come to all clinic visits
  - Women cannot be pregnant or nursing and must agree to use effective birth control methods throughout the study.
- You should avoid pregnancy or breastfeeding for 3 months after last vaccine dose.

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You will not be able to participate if you have:

- Been previously exposed to ETEC or *Vibrio cholerae* such as a past infection, an earlier research study, or through your work
- Allergies that may increase the risk of adverse reactions
- A positive blood test for Hepatitis B or C or HIV (the virus that causes AIDS)
- Abnormal clinical laboratory results
- Taken another experimental product within 30 days of starting this study
- Regular use of constipation, antacid or anti-diarrhea medications or treatments
- Abnormal stool patterns (fewer than 3/wk or more than 3/day)

During your screening medical check, you will be asked questions and have a physical examination to help determine if you meet the above criteria.

**How will I be compensated?**

- Civilian/Off-duty military compensation: Total: **up to \$1570**
- On-duty military personnel, as well as on-duty federal employees will be compensated a maximum of \$325

**What happens during the Screening Visit?**

The screening visit will include **medical history, physical examination with vital signs** (blood pressure, pulse, temperature and respirations) **and weight, and blood tests**. You will be asked to give less than 2 tablespoons of blood and the first of two induced stool procedures. You will also be asked to **report any medications**, including over the counter medications and contraceptives that you are currently taking and have taken recently. Females will be given urine pregnancy tests performed within one day of each planned shot and the shot will not be given if you are pregnant.

**What happens during the Study Period?**

If you are eligible and decide to participate, you will be **randomized (by chance like flipping a coin) to a group to receive the vaccine route indicated**. The time of your clinic visits for vaccination will be about 2 hours. **You will receive a vaccine shot/patch on Day 0, Day 21, and on Day 42**. The study shot will be given with a needle under the skin of your upper arm. You will have your vital signs (temperature, blood pressure) taken before each shot. You will remain in the clinic for 30 minutes after each shot for observation. Also, on Day 0 you will have blood taken (about 1 tablespoon) and a small amount of saliva measured to determine how your baseline immune responses. Additionally, you will need to bring in stool specimens on vaccination days following the collection instructions. **You will be asked to return to the clinic on Day 1, Day 7, Day 21 (2<sup>nd</sup> study injection), Day 22, Day 28, Day 42 (3<sup>rd</sup> study injection), Day 43, Day 49, Day 56 (second induced stool procedure), Day 70, and Day 180 for a telephone follow-up.**

The duration of the clinic follow-up visits will be about 30-45 minutes (Day 56 will be 2-4 hours for the induced stool procedure). The follow up phone call will take about 10 – 15 minutes.

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**What should I expect after vaccination?**

The vaccine (given by a shot with a needle under the skin of your upper arm) will be given in small doses first, and if determined to be safe, higher doses will be given. **Serious complications resulting from this type of shot are rare** but include infection, nerve injury, bleeding, skin discoloration, and scarring. **After injection, pain, tenderness, swelling, redness or bruising may occur at the injection site.** Fainting may occur following injection into the muscle particularly in young adults.

Vaccines given via a wet patch on the skin, have shown mild reactions such as skin rash at the site, itching, and change in skin coloration. There weren't general side effects such as headache, fever, vomiting or diarrhea. These reactions will most likely resolve on their own within a few days. There may be some risks that are unknown.

**An allergy to the vaccine is also possible.** An allergic reaction could include skin rash, difficulty breathing, or wheezing, a sudden drop in blood pressure, a fast pulse, swelling around the mouth, throat, or eyes, and sweating. An allergic reaction may be life threatening. Because of these possible reactions, you will be closely observed after each shot.

**The most common symptoms (adverse reactions) of vaccines containing similar products are pain, redness and swelling at the injection site as well as fatigue (tiredness), headache, muscle aches, joint pain, and stomach symptoms.**

**How do I schedule a visit and find out more information?**

Please call the Clinical Trials Center using the contact information below and provide the following information to the staff:

Name

Date of Birth

Gender – M or F

Address

Phone number

**Department of Clinical Trials, 6 am – 2:30 pm,  
Monday - Friday at 301-319-9335 or 301-319-9320**

*You may have your information stored in a database if you wish to be contacted for future studies.*