Recruitment Script

Title: A Phase 1 Dose-Escalating Study of dscCfaE, Co-Administered with and without LTR192G, by Transcutaneous Immunization (TCI) in Healthy Adult U.S. Volunteers

Investigator: Mark Riddle, MD DrPH, Enteric Diseases Department, NMRC

Background:

Escherichia coli, specifically Enterotoxigenic *E.coli* (ETEC) is a common cause of travelers' diarrhea. The military is trying to develop a vaccine to protect against ETEC. The ETEC vaccine is experimental. It will be given by a skin –patch. This is a first in human study. This study will take place at a clinic-type of facility in Silver Spring, MD. The vaccine will be given on your upper arm on days 0, 21 and 42. The patch will stay in place and will be removed by an investigator after 24 hours. Blood and stool specimens will be collected to test the body's ability to fight off infection or disease.

Objectives:

To test the safety and your body's response to this vaccine.

Duration:

One visit (screening) is required to see if you qualify for the study. If you are accepted into the study, you will receive three doses of vaccine over 6 weeks. You will visit the clinic on certain days after each vaccination. Six-months later we will contact you by phone for a brief follow-up on your status. The study will last about 9 months.

Number of people to be included into this study: 40

In order to participate in this study, 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.
- You will not be able to participate if you have:
    - Conditions which might make you more susceptible to having a side effect from the vaccine, such as acne, chronic skin diseases, abnormal skin findings (clinician judgment)
    - Acute skin conditions such as infections with fungus or bacteria, or trauma
    - A history of excessive scarring, "keloid" scars, poor wound healing or repeated skin infections
    - Been previously exposed to ETEC or *Vibrio cholerae* such as a past infection, an earlier research study, or through your work

NAVY MEDICINE HRPP
HRPP#: NMRC.2011.0004
Approval Date: 21 July 2011
Expiration Date: 01 March 2012
Verified By:

- 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 a detailed list of questions and have a physical examination to help determine if you meet the above criteria

Possible Risks:

This vaccine has 2 parts CfaE and mLT. This is the first time CfaE has been given to humans. mLT has been given to humans by skin and other routes. It is well tolerated. The vaccine has been given to many animals and the FDA has approved this trial in humans. Initially, we will start with a low-dose of CfaE to the first group, and will increase the dosesubsequently if the vaccine is tolerated.

Compensation:

Civilian/Off-duty military compensation: Total: $1345

On-duty military personnel, as well as federal employees will be compensated a maximum of $325 and will not be compensated for referring volunteers.

If you have any questions about the criteria you must meet to be in the study please ask me to repeat them now.

NAVY MEDICINE HRPP
HRPP#: NMRC 2011 .0004
Approval Date: 21 July 2011
Expiration Date: 01 March 2012
Verified By: