

Recruitment Script

Title: Safety and Tolerability of a Candidate Bioconjugate Vaccine Against *Shigella flexneri* 2a When Administered to Adult Volunteers

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Background:

Shigella is one of the most common causes of traveler's diarrhea, and infection can occur after eating or drinking contaminated food or water. The U.S. military is involved in developing a vaccine to protect against *Shigella* because soldiers are frequently sent to areas where they may be exposed to these bacteria. Once vaccines are approved, they could be used by any traveler or person living in areas with these types of bacteria.

The study is testing an experimental vaccine to protect against *Shigella*. The volunteers in this study will receive one of the following: experimental vaccine, experimental vaccine with alum adjuvant (to increase your body's immune response to the vaccine), or placebo. Volunteers will not know which they received until after the study. This will be the first time that this vaccine is given to humans. Similar vaccines have been given to humans and have been shown to be relatively safe.

Objectives:

This study will test safety of the vaccine and your body's response to this vaccine. The vaccine will be given by a shot to the muscle of your upper arm at 2 time points (study days 0 and 28). Blood will be collected to test the body's response to the vaccine.

Duration:

There are a total of 7 visits and 3 follow-up telephone calls. A screening visit is required to see if you qualify for the study. If you are accepted into the study, you will receive 2 shots of vaccine over a one month period. You will visit the clinic on specific days after each vaccination. We will also contact you by telephone six months after the second vaccination for a brief follow up on your status. The study will last about 7 months, not including screening.

Number of People to be included in this study: 30

Compensation:

Civilian/ Off-duty military and federal personnel: \$825 maximum

On-duty military/ federal employees: \$325 maximum

Inclusion/Exclusion Requirements:

You must meet all of the following eligibility requirements:

- Healthy adult between 18-50 years old
- Sign the written informed consent document
- Pass a written test of understanding and comprehension (70% correct or greater)
- Available for all follow-up calls and to come to all clinic visits
- Women cannot be pregnant or nursing and must agree to use effective and reliable birth control methods throughout the study. Women should avoid pregnancy or breastfeeding for 3 months after the last vaccine dose.

You will not be able to participate if you have:

- Been previously exposed to *Shigella* bacteria such as a past infection, an earlier research study, or through your work
- A positive blood test for Hepatitis B or C, HIV (the virus that causes AIDS), or HLA-B27
- Abnormal clinical laboratory results or physical exam results
- Taken another experimental product within 30 days of first vaccination
- A personal or family history of irritable bowel syndrome (IBS) or inflammatory arthritis
- An immunosuppressive illness, immunoglobulin deficiency, or a family history of congenital or hereditary immunodeficiency
- Abnormal bowel habits (fewer than 3 per week or more than 3 loose stools per day)
- History of allergies to any vaccine or alum adjuvant
- Previously received an experimental *Shigella* vaccine or live *Shigella* challenge
- A condition that requires the use of immunosuppressant drugs such as corticosteroids or chemotherapy
- Regular use of constipation, antacid or anti-diarrhea medications or treatments
- Have had treatment with immunoglobulins or blood products within 3 months from first vaccine injection

Possible risks:

There are risks associated with receiving this vaccine. There may be risks that are unknown at this time. Possible risks include allergic reaction, local reactions such as redness, induration, or swelling, systemic reactions such as fever, fatigue, malaise, and appetite change, and reactive arthritis. The risk of reactive arthritis is very low.

After each vaccination you will see a doctor in the clinic who will evaluate any reactions.

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