

"A Phase 1 Study to Evaluate the Safety, Tolerability, and Immunogenicity of a Tetravalent Dengue (Serotype 1, 2, 3, and 4) Plasmid DNA Vaccine (TVDV) Formulated with and without Vaxfectin®".

Background:

This study involves an experimental dengue vaccine. Dengue is a common infection affecting travelers to many areas of the world, including Southeast Asia, Central American, South American and the Caribbean. It is caused by a virus and is transmitted by a mosquito. Dengue can cause fever, tiredness, and even severe bleeding or death. It can pose a threat to military operations, and because this, the military is trying to develop a vaccine to protect against dengue.

This study involves a dengue vaccine that is experimental and has never been given to humans. It will take place at a clinic-type facility in Silver Spring, Maryland. The vaccine will be given in your arm or arms using a needle and blood samples will be collected to look at your body's response. The goals of this study are determine if the vaccine is safe and how your body responds to the vaccine.

Duration:

This study will last about 12 months including the time involved for screening. One or two clinic visits are required to see if you qualify for the study. If you are accepted into the study, you will receive 3 doses of vaccine over 3 months. You will visit the clinic 2 days and 7 days after each vaccination. A schedule will be given to you during the screening sessions that details the other days you will need to come to the clinic.

Requirements and Restrictions:

You must meet certain requirements to participate in this study. I am going to list them for you. You are not obligated to respond, but you may ask questions if you want me to clarify any of the following requirements or restrictions:

1. Volunteers must be at least 18 and not older than 50.
2. Volunteers must be in good health and have no significant current or past diseases.
3. Volunteers must not have had an infection or been vaccinated against Japanese Encephalitis, Yellow Fever, or Dengue.
4. Active duty military members need a signed approval memo from their supervisor to participate.
5. Volunteers must have access to the Naval Medical Research Center in Forest Glen, Maryland and Walter Reed Army Institute of Research (WRAIR), be willing to attend all of the required visits over 6-9 months, and be willing to refrain from participation in any other clinical studies involving investigational products or devices while participating in this study.
6. Volunteers cannot be pregnant or breastfeeding or anticipate becoming pregnant during the study.
7. Volunteers must not have donated or received blood, blood products, or plasma within 30 days prior to starting the study or plan on donating blood or plasma for at least 60 days after the last study vaccination.
8. Volunteers cannot participate if they plan to travel to an area where dengue is common during the study period.

There may be other reasons why you cannot participate in this study and those will be discussed at the screening visit.

Possible Risks:

There are risks associated with receiving this vaccine. This is the first time this dengue vaccine will be given to humans. Parts of the vaccine have been given to animals, and the Food and Drug Administration (FDA) has approved the use of this vaccine for this study.

We will start with a low dose of the vaccine in the first group of volunteers and then increase to a higher dose if the low dose is safe.

Based on experience with similar vaccines, mild reactions are expected. These generally include skin itching, pain at the injection site, and redness. These reactions will most likely resolve on their own within a few days. You may also experience other reactions, such as fever, headache, or tiredness. There may be some risks that are unknown.

After each vaccination you will see a physician in the clinic who will evaluate the number and type of reactions.

Compensation:

You will receive compensation for participating in this study. Civilians or off-duty military will be compensated \$1625:

- \$25 for screening visit (1 total)
- \$100 for each outpatient clinic visit with a blood draw (12 total)
- \$100 for each visit with vaccination and a blood draw (3 total)
- Bonuses for completion of Visits 12 (\$50) and Visit 16 (\$50)
- \$25 for referring another volunteer into the study (Referral Bonus)

On-duty military personnel will be compensated a maximum of \$725 (including screening compensation).