## Immunization Via Mosquito Bite With Radiation-attenuated Sporozoites (IMRAS)

## **Description**

clinicaltrials.gov/ct2/show/NCT01994525

Sponsor:

U.S. Army Medical Research and Development Command

Collaborators:

Seattle Children's Research Institute (SCRI)

**Bill & Melinda Gates Foundation** 

Principal Investigator: Nimfa Teneza-Mora, MD, Naval Medical Research Center

Information provided by (Responsible Party):

**U.S. Army Medical Research and Development Command** 

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Study Type: Interventional (Clinical Trial)

Actual Enrollment: 54 participants

Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: None (Open Label) Primary Purpose: Prevention

Official Title: Phase 1 Trial With Challenge to Assess the Safety and Biomarkers of Protection in Malaria-naïve Adults of Immunization Via Mosquito Bite With Radiation-Attenuated Plasmodium

Falciparum Sporozoites (IMRAS)

Actual Study Start Date: January 24, 2014

Actual Primary Completion Date: December 20, 2016

Actual Study Completion Date: February 2017

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This is a Phase 1 open-labeled study. In addition to safety and tolerability of Plasmodium falciparum Sporozoites (PfRAS), this study is a comprehensive, systems biology-based effort to identify and validate biomarkers of protection with PfRAS immunization, comparing sterility protected to nonprotected study subjects. The goal of the trial design is to achieve approximately 50% sterile protection in order to facilitate the identification of biomarkers and correlates of protection.

Following true-immunization or mock-immunization, study subjects and nonimmunized infectivity controls will receive a challenge via the bites of 5 An stephensi mosquitoes carrying infectious P falciparum sporozoites within a controlled clinical environment (controlled human malaria infection, CHMI) to determine the level of sterile protection.

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