

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](#)

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

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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