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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