

P. vivax study information to potential volunteers

Principle Investigator: Dr. Chuang

Background:

The purpose of this research study is to demonstrate that people can get malaria safely through the bites of infected mosquitoes. This method is called “malaria challenge”, and if successful, will be used to test whether new vaccines or drugs for malaria can indeed protect from or treat malaria. The particular strain of malaria that we are studying is called *Plasmodium vivax* (or in short, *P. vivax*), which is less severe than another strain used in past challenges called *P. falciparum*; even so, volunteers will be monitored closely. The study will be conducted at the Clinical Trial Center (CTC) at Walter Reed Army Institute of Research (WRAIR).

This is the first systematic study in the United States importing mosquitoes from Thailand for development of *P. vivax* challenge. We are inviting healthy volunteers who have not been exposed to malaria within the last 5 years to take part in this study. This study is divided into 2 groups of 6 people each. The doctor in charge of this project is Dr. Ilin Chuang from the United States Military Malaria Vaccine Program, Naval Medical Research Center (NMRC).

To participate in this study you must be:

You must be within the study age requirements, 18-55 years

You must be in good health

You must not have had malaria before within the last 5 years

You must not currently be under treatment for any clinically significant medical conditions

You must not abuse drugs or alcohol

You must not ever have tested positive with HIV or hepatitis B or C

Some medications may disqualify you from participating

If you are a female, you cannot be pregnant or plan on becoming pregnant during the study

In addition, there are other requirements that the study doctors will go over with you when you come for screening.

What will I be asked to do if I join this research study?

The first step is to come to CTC for screening where we will go over what this study is about and then ask for your agreement to participate in this study. After you have read and signed the consent forms, you will undergo a medical evaluation that includes review of your medical history, a physical examination, and blood tests. This is done to ensure that you are in good health and are able to safely participate in this study. If you are found to be eligible after the screening, two days before the challenge, you will come to the CTC where a brief physical exam and evaluation will be performed.

All eligible volunteers will go on to be challenged with *P. vivax* malaria-infected mosquitoes. During the challenge, initially we allow 5 mosquitoes to bite you for 5 minutes. If all 5 mosquitoes do not bite you we will

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let more mosquitoes bite you for 5 minutes until a total of 5 malaria-infected mosquitoes have bitten you. If you are part of the first group, you will get 5 infective mosquito bites. If fewer than 100% of all the volunteers from the first group develop malaria infection and if you are in the second group, you will get 10 infected bites. In the days after the challenge, we will check you for signs of malaria infection. Malaria usually develops between 9 and 14 days after an infected mosquito bites you. **WE EXPECT YOU TO DEVELOP MALARIA.**

Frequent follow-up visits begin the day after the challenge in the CTC. To ensure your safety, starting the evening of day 9 after challenge, we will move you into a local hotel for 10 days along with the clinical research team (doctors, nurses, study coordinators, etc.). All volunteers are required to spend every night at the hotel; during the day, you can leave the hotel to do whatever you wish. The hotel stay allows the doctors and medical staff to evaluate you promptly anytime during the day or night. You must check in with the study staff in the hotel each morning for your daily evaluation. We will ask you how you are feeling and draw blood to check for parasites. In the afternoon, we will contact you to check on how you are feeling and to tell you if you have parasites in your blood and thus need treatment. If malaria parasites are found in your blood, you will be treated with 2 drugs to eliminate the parasites from your blood and observed for treatment until you complete both medications. After you have been treated for malaria, we will see you in the clinic approximately 6 more times. The last study visit will occur approximately 6 months after the challenge.

How long will I be in this study?

If you qualify to be enrolled in the study, the total time you may be in the study will be approximately 9 months beginning with the screening; complete details will be provided during screening.

Will I get any payment for participating in the study?

For each visit, you will receive compensation for your time and efforts ranging from \$20 to \$250; complete details will be provided during screening. The total compensation varies depending on when you develop malaria; the maximum compensation will be around \$2500. Active duty military personnel will be compensated the same as non-military personnel only for visits which occur during off-duty hours. Otherwise military members will receive compensation for blood draws (\$50 per visit) during duty hours.