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First in-human vaccine study for malaria caused by Plasmodium vivax

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Walter Reed Army Institute of Research (WRAIR) researchers recently published the results of testing a *Plasmodium vivax* malaria vaccine candidate in a human challenge model.

A vaccine to prevent infection and disease caused by *P. vivax* is critical to reduce sickness and mortality from vivax malaria, a common cause of malaria among deployed service members. While malaria no longer poses a significant threat in developed countries, it affects millions of people every year around the world. *P. vivax* malaria is challenging to control because it can be dormant, causing no symptoms, and then become active causing symptomatic malaria weeks to months after initial infection.

The vaccine candidate developed by WRAIR and tested jointly with GlaxoSmithKline (GSK) to prevent vivax malaria infection is the first in-human study of its kind under an investigational new drug application with the US Food and Drug Administration. WRAIR investigators immunized 30 volunteers with three doses of the vaccine candidate. Malaria is only transmitted through the bite of a female mosquito. Immunized volunteers took part in WRAIR's well-established controlled human malaria infection (CHMI) model where they were bitten by malaria-infected mosquitoes. The efficacy of the vaccine candidate was then determined based on whether or not volunteers developed malaria by looking at blood smears or if it took longer for malaria parasites to appear in the blood.

"This study represents the first vaccine study to test the effectiveness of a *P. vivax* vaccine candidate in humans using controlled human malaria infection," said Lt. Col. Jason W. Bennett, the study's lead investigator. The study's results were published today in the journal *PLOS Neglected Tropical Diseases*. Unlike P. falciparum where a CHMI model is well established, the *P. vivax* CHMI model must rely on blood donations from infected humans to initiate infections in mosquitoes.

For this trial, the WRAIR investigators worked with the WRAIR overseas lab in Bangkok, Thailand, the Armed Forces Research Institute of Medical Sciences (AFRIMS), to acquire *P. vivax*-infected mosquitoes which were then transported to WRAIR for the malaria challenge. The vaccine candidate was well tolerated in all volunteers and generated robust immune responses. While the vaccine candidate did not prevent malaria infection, it did significantly delay parasitemia in 59% of vaccinated subjects.

Col. Robert Paris, director of the US Military Malaria Research Program at WRAIR, is optimistic that an improved vaccine can be designed. "Findings from the analysis of the immune response of vaccinated subjects have given us clues to improve vaccine candidates and studies are now underway at WRAIR to develop next generation vivax vaccines," says Dr. Paris, "Vaccines and antimalarial drugs are both critical needs for the DoD to protect service members from malaria."

Malaria challenge models require effective treatment for any resulting malaria infections. Investigators were also able to demonstrate that individuals with low or absent levels of a specific liver enzyme were unable to convert primaquine to an active drug form to kill the dormant stage of the parasites. These volunteers were more likely to experience vivax malaria relapse. The clinical data in this study is the first to show that differences in a person's genetics can result in primaquine treatment failure. Despite this newly identified limitation, primaquine remains the

only FDA-approved drug to treat the dormant stages of vivax malaria.

WRAIR remains dedicated to developing vaccines, cures, and other products to eradicate and curb the transmission of infectious diseases. Decades of research at WRAIR have culminated in many effective products, including vaccines for yellow fever, dengue fever, and Japanese encephalitis. This study demonstrates WRAIR's continued dedication to malaria prevention and marks an important step towards an effective *P. vivax* vaccine.

Provided by The U.S. Military HIV Research Program (MHRP)

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