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Malaria vaccine candidate safe and immunogenic following first-in-human trials

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Capt. Aaron Sanborn, clinical research coordinator with the Walter Reed Army Institute of Research Clinical Trials Center, prepares FMP013 malaria vaccines, April 27, 2021. Credit: U.S. Army photo by Mike Walters/Released

Researchers from the Walter Reed Army Institute of Research (WRAIR) report the malaria vaccine FMP013 antigen and ALFQ adjuvant combination appears safe and immunogenic for adults in the first-in-human evaluation results published in the *Vaccine* journal.

Although malaria control efforts yielded steady progress over the past decade, instability introduced by the COVID-19 pandemic has resulted in a resurgence of malaria incidence and mortality. The World Health Organization estimated that, there were 241 million cases of malaria resulting in 627,000 deaths in 2020 alone.

Vaccines continue to be pursued as an important component of the portfolio to overcome these staggering numbers. While impactful, first-generation efforts, such as RTS,S/AS01 (Mosquirix, GSK), provide only moderate (30-50%) protection which wanes within months.

"The search for improved vaccine strategies remains a priority," said Col. Jason Regules, Biologics Research and Development Branch Director.

For more than three decades U.S. Army researchers have developed malaria vaccine candidates, testing their safety and ability to elicit protective immune responses against infection. The current FMP013 candidate primes vaccinated humans to produce antibodies against the circumsporozoite protein (CSP) of the malaria parasite Plasmodium falciparum.

"The vaccine design broadens the host immune response to epitopes that were not included in the RTS,S vaccine and targeting these additional susceptible epitopes on CSP could be key to an improved vaccine," said Dr. Sheetij Dutta, Chief of the Structural Vaccinology Laboratory and inventor of the FMP013 antigen.

The vaccine also contains the adjuvant Army Liposome Formulation with QS-21, or ALFQ, which was developed at WRAIR by the Military HIV Research Program. "ALFQ displays promising immune-enhancing effects and is now being tested with vaccines against a number of infectious diseases," said Dr. Gary Matyas, Chief of the Adjuvants and

Formulation Section.

A Walter Reed Army Institute of Research, Clinical Trials Center researcher holds a vial of the FMP013 malaria vaccine, April 27, 2021. Credit: U.S. Army photo by Mike Walters/Released

Preclinical studies demonstrated ALFQ to be safe and strongly potent as a vaccine adjuvant, supporting its use in this initial human trial.

"Both high and low dose of FMP013 antigen and the ALFQ adjuvant were found to be safe and well tolerated by adults," said Maj. Jack Hutter, the clinical trial principal investigator. "Both groups exhibited robust humoral and cellular immunological responses and compared favorably with historical responses reported for RTS,S/AS01."

Follow-on safety and efficacy test results in malaria-naïve adults are expected to be released by the end of the year.

More information: Jack N Hutter et al, First-in-human assessment of safety and immunogenicity of low and high doses of Plasmodium falciparum malaria protein 013 (FMP013) administered intramuscularly with ALFQ adjuvant in healthy malaria-naïve adults, *Vaccine* (2022). DOI: 10.1016/j.vaccine.2022.08.048

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