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Phase 1 Clinical Trial of WRAIR-developed COVID-19 vaccine begins

The Army's vaccine has potential to offer broad protection from SARS-CoV-2, and may be adapted to protect from other coronaviruses

SILVER SPRING, Md. – A unique vaccine to protect against COVID-19 begins clinical testing Tuesday, 6 April, at the [Walter Reed Army Institute of Research](#) (WRAIR), part of the [U.S. Army Medical Research and Development Command](#). Scientists developed a nanoparticle vaccine, based on a ferritin platform, which offers a flexible approach to targeting multiple variants of SARS-CoV-2 and potentially other coronaviruses as well.

The vaccine, called Spike Ferritin Nanoparticle (SpFN), stands out in the COVID-19 vaccine landscape. Its multi-faced sphere design allows repetitive, ordered presentation of the coronavirus spike protein to the immune system, a strategy that may help provide broader protection.

“Even before recent COVID-19 variants were identified, our team was concerned about the emergence of new coronaviruses in human populations, a threat that has been accelerating in recent years” said Dr. Kayvon Modjarrad, director of the Emerging Infectious Diseases Branch (EIDB) at WRAIR who leads the Army’s COVID-19 vaccine research efforts and co-invented the vaccine with WRAIR structural biologist Dr. Gordon Joyce. “That’s why we need a vaccine like this: one that has potential to protect broadly and proactively against multiple coronavirus species and strains.”

Pre-clinical studies¹ indicate that SpFN induces highly potent and broad neutralizing antibody responses against the virus that causes COVID-19 infection, as well as three major SARS-CoV-2 variants and SARS-CoV-1 virus.

The phase 1 study is being conducted at WRAIR’s Clinical Trials Center and will enroll 72 healthy adult volunteers ages 18-55. Participants will be randomly placed in placebo or experimental groups.

“This first in human clinical trial of a novel vaccine for SARS-CoV-2 demonstrates the strength of WRAIR’s ability to very quickly transition exciting basic science discoveries to the clinic with the promise of developing a public health tool for long-term pandemic control,” said Dr. Nelson Michael, director of WRAIR’s Center for Infectious Diseases Research. WRAIR is also providing expertise and support to the interagency U.S. federal government response aimed at accelerating the development of other COVID-19 vaccines, therapeutics and diagnostics.

“We are in this for the long haul,” said Modjarrad. “We have designed and positioned this platform as the next generation vaccine, one that paves the way for a universal vaccine to protect against not only the current virus, but also counter future variants, stopping them in their tracks before they can cause another pandemic.”

About the Study:

The clinical trial of SpFN is sponsored by the U.S. Army Medical Research and Development Command (USAMRDC). The vaccine was developed by the Walter Reed Army Institute of Research (WRAIR)

Emerging Infectious Diseases Program with support from the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc (HJF). Funding was provided by the Defense Health Agency and was executed, in part, through a cooperative agreement between WRAIR and HJF (CA# W81XWH-18-2-0040).

The trial is registered on clinicaltrials.gov: <https://clinicaltrials.gov/ct2/show/NCT04784767>

¹Preclinical data on SpFN: <https://www.biorxiv.org/content/10.1101/2021.03.24.436523v1>

About the Walter Reed Army Institute of Research:

The Walter Reed Army Institute of Research (WRAIR), part of the U.S. Army Medical Research and Development Command, provides unique research capabilities and innovative medical solutions to a range of Force Health Protection and Readiness challenges currently facing U.S. Service Members, along with threats anticipated during future operations. WRAIR has created a model of vaccine and therapeutic development that is unique, nimble, and responsive to dynamically evolving infectious disease threats of military importance. Leveraging its expertise, facilities, and international network, the Institute has helped developed many vaccines and drugs in use today by military and civilian medicine around the globe. In 2018, the Emerging Infectious Diseases Branch (EIDB) was created with an explicit mission to survey, anticipate and counter the growing threat of emerging infectious diseases of key importance to U.S. forces in the homeland and abroad.