MERS-CoV vaccine is safe and induces strong immunity in Army-led first-in-human trial

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A Middle East respiratory syndrome coronavirus (MERS CoV) vaccine candidate was shown to be safe, well-tolerated, and induced a robust immune response in a Phase 1 first-in-human clinical trial. Initial findings from the trial were published today in *The Lancet Infectious Diseases*.

The study, conducted at the Walter Reed Army Institute of Research (WRAIR) Clinical Trials Center, evaluated a candidate DNA vaccine (GLS-5300) co-developed by GeneOne Life Science Inc. and Inovio Pharmaceuticals. Though other vaccine candidates have previously been tested for use in camels, which are the suspected source of the virus that causes MERS, this is the first vaccine candidate to be tested in humans.

Seventy-five healthy adult volunteers received one of three dosages of the candidate vaccine at three time points (initial, one month, three months) and were followed for one year after final vaccination. Vaccinations were given with an electrical impulse to help with vaccine uptake. Vaccine-induced immune responses were compared to those of individuals who had recovered from natural MERS CoV infection.

The GLS-5300 MERS CoV vaccine was well tolerated with no major side effects reported by the volunteers. More than 85 percent of volunteers exhibited a detectable immune response to MERS CoV after just two vaccinations. This immune response persisted throughout the

study and was similar in magnitude to the response seen in survivors of natural MERS CoV infection.

MERS is a severe respiratory disease akin to the Severe Acute Respiratory Syndrome (SARS) and was first identified in Saudi Arabia in 2012. MERS CoV has infected more than 2,200 people and killed nearly 40% of those infected. There are currently no licensed vaccines or specific treatments for MERS. MERS has been identified as a priority disease by the World Health Organization (WHO) and as a top target for vaccine development by the Coalition for Epidemic Preparedness Innovations (CEPI).

"The world witnessed the emergence and devastation of SARS in 2002 and then MERS ten years later. MERS hasn't gone away, and there's every indication that the family of viruses to which SARS and MERS belong, coronaviruses, are here to stay," said Dr. Kayvon Modjarrad, director of WRAIR's Emerging Infectious Diseases Branch, the principal investigator of the study and first author on the publication. He added, "Military personnel are at particular risk for MERS, given the deployments to the Middle East and South Korea where the largest MERS outbreaks have occurred. This study is, therefore, an important advancement for the U.S. Army, the military community as a whole and global stakeholders in the research and development of both MERS and corona virus countermeasures."

The GLS-5300 MERS-CoV product is a DNA vaccine candidate, which allows for rapid design and production in response to emerging infectious diseases. Underscoring the potential for rapid deployment of DNA vaccines, GLS-5300 was advanced into the clinic within nine months of preclinical vaccine candidate selection. The promising results from this study have prompted advancement to a second Phase I/IIa trial in South Korea and a Phase II study in the Middle East.

Emerging infectious diseases such as MERS pose an ongoing threat to military operations and readiness, and WRAIR's Emerging Infectious Diseases Branch (EIDB) develops vaccines, drugs and diagnostics to address these threats. The branch is also studying and developing countermeasures for Ebola, Marburg, Zika and Lassa, among other emerging threats.

Provided by Walter Reed Army Institute of Research