

Human clinical trial of DNA-MVA HIV vaccine candidate begins

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A Phase I study, called RV262, recently began to evaluate a combination DNA prime/MVA vector boost vaccine regimen that was developed to protect against diverse subtypes of HIV-1 prevalent in North America, Europe, Africa and South America.

The National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH), is sponsoring the study, which will enroll 92 total participants and is designed to assess safety and immune responses. The study is being conducted by the U.S. Military HIV Research Program (MHRP) through its clinical research network in the U.S., East Africa and Thailand.

This clinical trial was designed to test a unique prime-boost preventive HIV [vaccination strategy](#) aimed at global coverage. The prime is a plasmid DNA vaccine, PENNVAX™-G, and the boost is a virus vector vaccine, Modified Vaccinia Ankara-Chiang Mai Double Recombinant (MVA-CMDR). Together, the vaccines are designed to deliver a diverse mixture of antigens for HIV-1 subtypes A, B, C, D and E.

Taken separately, DNA-based and MVA-based strategies have been shown to be safe and immunogenic in pre-clinical and clinical trials. Researchers hope they can enhance immune responses by using this prime-boost strategy. Another distinguishing feature of this study is the use of different HIV antigens during the priming (A,B,C,D) and boosting (A/E), which is being studied as a means to increase the breadth of the [immune response](#).

"We hypothesize that this vaccine regimen, which has subtype-mismatched inserts, will facilitate the emergence of subdominant epitopes and increase the overall breadth of the immune response," noted Dr. Mary Marovich, Chief of the Department of Vaccine Research and Development at MHRP and the Protocol Chair for the study.

The DNA vaccine was designed in Prof. David B. Weiner's laboratory at the University of Pennsylvania and licensed by Inovio Pharmaceuticals for further clinical product development. The boost vaccine component, based on Modified Vaccinia Ankara (MVA), is a modified version of the smallpox vaccine that has been used safely and effectively to eradicate that disease worldwide. Researchers at MHRP and NIAID developed the MVA vaccine.

Historically, DNA vaccine potency has been constrained by the inability to deliver enough DNA into cells, which express the antigens coded by the DNA. To address this, researchers will also test two intramuscular delivery methods for the DNA prime (PENNVAX™-G) to compare their effects on immune response. The two devices that will be tested in this study are the Biojector® 2000 and the CELLECTRA® EP (electroporation) device.

The Biojector is a needle-free injection system that has FDA clearance for delivering vaccines and other injected medications. The CELLECTRA EP system is an intramuscular electroporation device currently being evaluated in [clinical trials](#) as an alternative vaccine delivery system to increase immune responses above those elicited by standard needle and syringe injections. Electroporation involves the application of controlled, millisecond electrical pulses to cells to enhance their uptake of the vaccine.

"We are very excited about the launch of this important clinical trial

exploring the role of newer [HIV](#) vaccine approaches building on the success of the RV144 Thai prime boost trial," said COL Nelson Michael, Director of MHRP and the Division of Retrovirology at the Walter Reed Army Institute of Research (WRAIR). "The role of electroporation as a method of delivery of the priming DNA vaccine will be an especially critical factor to assess in this initial phase I safety and immunogenicity trial."

Once the [vaccine](#) combination has been assessed as safe and acceptable in 12 HIV-uninfected participants in the U.S., the study will begin at four MHRP sites: Kericho, Kenya; Kampala, Uganda; Mbeya, Tanzania; and Bangkok, Thailand. Twenty healthy, HIV-uninfected participants will be enrolled at each of these sites for a total of 80 international participants.

This clinical trial is a collaboration that includes Bioject Medical Technologies Inc., Inovio Pharmaceuticals, Inc., The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., NIAID and the U.S. Army/MHRP.

Provided by Henry M. Jackson Foundation for the Advancement of Military Medicine

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