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Human trials initiated for new HIV vaccine

Clade C HIV Envelope Protein Being Tested in Phase I Clinical Trial

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In the first clinical trial of an injectable vaccine containing trimeric HIV envelope protein (gp140) relevant to the predominant strain of HIV in Africa, researchers from four UK academic centers (St George's University London, Imperial College, Hull York Medical School (HYMS; University of York) and the Medical Research Council Clinical Trial Unit) and from the Infectious Disease Research Institute (IDRI) have come together to evaluate whether the vaccine is safe for use in human volunteers. If the vaccine does prove to be safe, and induces appropriate immunity, it could be considered for further testing and eventually be evaluated for its effectiveness as a vaccine for protecting women against HIV infection in Sub-Saharan Africa.

The trial, which is funded by the Wellcome Trust and goes by the name MUCOVAC2, is evaluating a vaccine that contains the HIV trimeric gp140 protein CN54, representative of Clade C strains of the virus. This clade of HIV is the most prevalent type of virus in Sub-Saharan Africa and responsible for the greatest number of infections globally. The trimeric protein represents the major target for antibodies on the viral surface.

The vaccine candidate will be formulated with an adjuvant known as GLA, developed by IDRI to enhance immune responsiveness following intramuscular injection. GLA formulations have been previously tested clinically with promising results.

Globally, Clade C HIV has caused the world's worst HIV epidemics and has infected half of the 34 million people living with HIV. In Sub-Saharan Africa, Clade C virus has infected the majority of adults with HIV and is predominant in India, China and South America. Vaccine candidates relevant to the Sub-Saharan epidemic are critically important to prevent large scale HIV infection in the fight against the global HIV epidemic.

MUCOVAC2, which is now screening potential participants, will enroll 36 healthy, HIV-negative women aged 18-45 years at St George's University of London and the HYMS Experimental Medicine Unit at York Hospital. Researchers will evaluate the vaccine's safety and determine the quality and magnitude of induced immune responses. The study is expected to take less than a year to complete with results available early 2013.



Women will be randomly assigned to receive the vaccine by intramuscular injection, intranasal immunization through the application of liquid drops to the nose, or a combination of intramuscular injection followed by intravaginal immunization through the application of a gel-based formulation. This will enable researchers to compare the safety and levels of induced antibodies in the blood and vaginal secretions generated by the different vaccine approaches.

Leading the study for St George's is Dr. Catherine Cosgrove, with Professor Charles Lacey leading the study at York.

"Globally, women comprise half of the 34 million people living with HIV. In Sub-Saharan Africa, women represent nearly 60 percent of adults with the virus. Our collaboration marks an important juncture for the field as we begin to assess which routes of immunization may provide the best responses to protect women," remarked Professor Robin Shattock, who is Chair in Mucosal Infection and Immunity at Imperial College, and who leads the consortium which developed the MUCOVAC2 trial.

Additional information about MUCOVAC2 and other UK vaccine studies is available at <http://www.helpmakehistory.mrc.ac.uk>.

About IDRI

The Infectious Disease Research Institute (IDRI) is a Seattle-based not-for-profit organization committed to applying innovative science to the research and development of products to prevent, detect, and treat infectious diseases of poverty. By integrating capabilities, including early stage drug discovery, preclinical testing, manufacturing, and clinical trials, IDRI strives to create an efficient pathway bringing scientific innovation from the laboratory to the people who need it most. For more information, visit www.idri.org.

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