NIH-Sponsored Trial of Nasal COVID-19 Vaccine Opens

Candidate vaccine could provide enhanced breadth of protection against emerging SARS-CoV-2 variants.

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A Phase 1 trial testing the safety of an experimental nasal vaccine that may provide enhanced breadth of protection against emerging variants of SARS-CoV-2, the virus that causes COVID-19, is now enrolling healthy adults at three sites in the United States.

The National Institutes of Health (NIH) is sponsoring the first-in-human trial of the investigational vaccine, which was designed and tested in pre-clinical studies by scientists from NIH's National Institute of Allergy and Infectious Diseases (NIAID) Laboratory of Infectious Diseases.

"The rapid development of safe and effective COVID-19 vaccines was a triumph of science, and their use greatly mitigated the toll of the pandemic," said NIAID Director Jeanne M. Marrazzo, MD, MPH. "While first-generation COVID-19 vaccines continue to be effective at preventing severe illness, hospitalizations, and death, they are less successful at preventing infection and milder forms of disease. With the continual emergence of new virus variants, there is a critical need to develop next-generation COVID-19 vaccines, including nasal vaccines, that could reduce SARS-CoV-2 infections and transmission."

The study aims to enroll 60 adult participants, ages 18 to 64 years old, who previously received at least three prior doses of an FDA-approved or authorized mRNA COVID-19 vaccine. The trial sites are Baylor College of Medicine, Houston; The Hope Clinic of Emory University, Decatur, Georgia; and New York University, Long Island. Hana M. El Sahly, MD, at the Baylor College of Medicine Vaccine Research Center, is leading the study.

Study volunteers will be divided into three cohorts. Those in the first cohort will receive one dose of the investigational vaccine delivered in a nasal spray at the lowest dosage, with enrollees in the next two cohorts receiving progressively higher doses. During seven follow-up visits over about one year, scientists will measure how well the vaccine candidate is tolerated, and if it generates an immune response in the blood and in the nose.

The investigational vaccine, MPV/S-2P, uses murine pneumonia virus (MPV) as a vector to deliver a version of the SARS-CoV-2 spike protein (S-2P) stabilized in its prefusion conformation. MPV does

not cause disease in humans or non-human primates but does have an affinity for epithelial cells that line the respiratory tract and may be effective in delivering vaccine to the places where natural coronavirus infections begin.

In pre-clinical non-human primate studies, MPV/S-2P was safe and well tolerated. It produced robust systemic immune responses, including SARS-CoV-2-directed antibodies, as well as local immunity in cells in the mucosal tissues lining the nose and respiratory tract. Studies in humans and animals suggest that mucosal immunity is more effective than systemic immunity in controlling replication of respiratory viruses.

This is the first NIAID clinical trial to be conducted as part of the U.S. Department of Health and Human Services (HHS) Project NextGen. Led by the Biomedical Advanced Research and Development Authority, part of the HHS Administration for Strategic Preparedness and Response, and NIAID, Project NextGen is a coordinated effort between the federal government and the private sector to broaden the pipeline of new, innovative vaccines and therapeutics. Through Project NextGen, NIAID plans to facilitate clinical development of promising next-generation COVID-19 vaccines in Phase 1 and 2 trials.

More information about the trial is available at clinicaltrials.gov using the identifier NCT06441968.

NIAID conducts and supports research — at NIH, throughout the United States, and worldwide — to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses. News releases, fact sheets and other NIAID-related materials are available on the NIAID website.

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