Experimental Nasal Influenza Vaccine Tested in Kids, Teens

NIAID-Supported Phase 1 Trial of Potential Broadly Protective Vaccine
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An early-stage clinical trial testing the safety and immune-stimulating ability of an experimental nasal influenza vaccine in healthy 9- to 17-year-old children and teens has begun enrolling participants at a Vaccine and Treatment Evaluation Unit (VTEU) site at Saint Louis University, St. Louis, Missouri. The VTEU is funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health.

Annual vaccination against influenza is recommended for everyone over six months of age. However, because the flu virus changes from year to year, vaccines must be reformulated annually to take account of those changes. When mismatches occur, vaccine effectiveness may suffer. “We are hopeful that newer kinds of influenza vaccines, such as the candidate being tested in this trial, will provide protection even if their components do not precisely match the currently circulating influenza virus strains,” said NIAID Director Anthony S. Fauci, M.D.

Principal investigator Daniel Hoft, M.D., Ph.D., leads the clinical trial, which will enroll 50 participants. Half will receive the candidate nasal vaccine and the other half will receive a dose of inactive saline solution delivered as nasal spray. Neither the study staff nor volunteers will know whether a participant has received the experimental vaccine or placebo saline solution. All volunteers will receive an intramuscular injection of a licensed, quadrivalent seasonal influenza vaccine three months after receiving the initial nasal vaccine or placebo. An important objective of the study is to determine whether the combination of the licensed and experimental vaccine leads to broader protection against influenza viruses compared with the licensed vaccine alone. Investigators will perform an array of tests on volunteer blood samples at four time points following the first vaccination as well as three weeks after the second vaccination. They will look for evidence of immune responses from antibody-producing cells as well as from the cellular arm of the immune system.

The investigational vaccine, developed by FluGen, Inc. of Madison, Wisconsin, is made from a strain of seasonal influenza virus (H3N2) that has been genetically designed to replicate only once in the body. Studies in animals showed that the “single replication” virus does not cause disease but nevertheless prompted a robust immune response akin to that of a natural influenza infection. Investigators hypothesize that volunteers who receive the candidate vaccine will have a robust immune response not only against H3N2 strains that match those in the vaccine but also against influenza strains that are mismatched to the vaccine strain. A previous Phase 1 trial of this candidate vaccine in healthy adults showed that it was safe and generated a robust immune response and a Phase 2 trial in healthy adults is currently underway (that trial is not supported by NIAID.)

For more information about this trial of an experimental influenza vaccine in older children and adolescents, visit ClinicalTrials.gov(link is external) and search on identifier NCT03553940(link is external). The VTEUs are funded by NIAID through contract number HHSN272201300021.