U.S. Dept. of Health and Human Services: Clinical trial evaluating monkeypox vaccine begins

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A clinical trial evaluating alternative strategies for administering the JYNNEOS monkeypox vaccine to increase the number of available doses has begun enrolling adult volunteers. The trial, which will enroll more than 200 adults across eight U.S. research sites, is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. JYNNEOS is manufactured by Bavarian Nordic, based in Copenhagen. It is approved by the U.S. Food and Drug Administration for the prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection.

JYNNEOS contains an attenuated orthopoxvirus called modified vaccinia Ankara (MVA), which does not replicate in human cells. It is approved for administration by two subcutaneous (in the tissue beneath the skin) injections 28 days apart; however, the FDA recently authorized intradermal (between layers of the skin) administration of the vaccine for adults, which expands the number of people who can be vaccinated with the currently limited supply. This alternative intradermal dosing regimen uses one-fifth of the standard dose used for subcutaneous administration, allowing health care providers to administer up to five times the number of vaccine doses per vial of JYNNEOS vaccine. NIH-supported researchers demonstrated in a 2015 publication
< https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdoi.org%2F10.1016%2Fj.vaccine.2015.06.075&data=05%7C01%7Cjennifer.routh%40nih.gov%7C2b6b52c074a6497de90908da76edcfe8%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C637953061013157564%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%

7C%7C&sdata=ZKJhDsqUN4Yk5I8dYjwdWpNF9fvcvU2585fZpp3%2BQow%3D&reserved=0> that intradermal administration at one-fifth of the standard dose induced an immune response in recipients that was comparable to the subcutaneous method of administration.

“To halt the global outbreak of monkeypox and to help protect those at risk of infection, we need to ensure we have an adequate supply of monkeypox vaccine,” said NIAID Director Anthony S. Fauci, M.D. “NIAID’s trial of JYNNEOS will provide important information on the immunogenicity, safety, and tolerability of alternative dosing approaches that would expand the current supply of vaccine.”

The Centers for Disease Control and Prevention has reported 20,733 cases of monkeypox in the United States since May 2022. The global outbreak is primarily affecting men who have sex with men. The virus usually causes painful skin lesions and flu-like symptoms. Serious complications—which have been rare in the United States—can include dehydration, bacterial infections, pneumonia, brain inflammation, sepsis, eye infections and death. Historically, the virus is known to be transmitted from person to person through direct contact with skin lesions, body fluids, and respiratory droplets and by indirect contact with items such as contaminated clothing or bedding. Preliminary analyses indicate that sexual transmission may be playing a role in the current outbreak.

Adults ages 18 to 50 years who have not been vaccinated against smallpox or monkeypox previously are eligible to enroll in the NIAID trial. Investigators aim to include a demographically diverse group of volunteers that represents those affected by monkeypox. All trial participants will receive the JYNNEOS vaccine in some form. Participants will be assigned at random to one of three study arms:

–One arm will receive the standard, licensed regimen of 1×108 infectious virus particles administered subcutaneously.

–Another arm will receive 2×107 infectious virus particles (one-fifth of the standard regimen) administered intradermally, the regimen recently authorized by the FDA.

–A third arm will receive one-tenth (1×107 infectious virus particles) of the standard regimen of JYNNEOS administered intradermally.

Investigators will assess whether the peak immune responses induced in recipients receiving the vaccine intradermally are at least as good as those induced by the

licensed subcutaneous regimen and will compare the relative safety and tolerability of the different regimens.

Volunteers will be asked to participate in eight study visits over the course of a year where they will undergo physical examinations and provide blood samples for laboratory evaluations. An independent Data and Safety Monitoring Board (DSMB) will monitor participant safety throughout the duration of the study.

The trial will enroll volunteers at the following sites:

–Saint Louis University in Missouri

–Baylor College of Medicine in Houston

–Brigham and Women's Hospital in Boston

–The NIH Clinical Center in Bethesda, Maryland

–George Washington University in Washington, D.C.

–Vanderbilt University in Nashville, Tennessee

–The Hope Clinic at Emory University in Decatur, Georgia

–The University of California, San Diego

Investigators anticipate the trial will take 15 months to complete; however, initial results could be available in early 2023. For more information, please visit clincialtrials.gov and search identifier NCT05512949 <https://clinicaltrials.gov/ct2/show/NCT05512949?term=NCT05512949&draw=2&rank=1>.

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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