Monkeypox Treatment Trial Begins in the Democratic Republic of the Congo

The NIH and local researchers are collaborating to evaluate the antiviral drug TPOXX.

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A clinical trial to evaluate the antiviral drug tecovirimat, also known as TPOXX, in adults and children with monkeypox has begun in the Democratic Republic of the Congo (DRC). The trial will evaluate the drug's safety and its ability to mitigate monkeypox symptoms and prevent serious outcomes, including death.

The National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health, and the DRC's National Institute for Biomedical Research (INRB) are co-leading the trial as part of the government-to-government PALM partnership. Collaborating institutions include the U.S. Centers for Disease Control and Prevention (CDC), the Institute of Tropical Medicine Antwerp, the aid organization Alliance for International Medical Action (ALIMA) and the World Health Organization (WHO).

TPOXX, made by the pharmaceutical company SIGA Technologies, Inc. (New York), is approved by the U.S. Food and Drug Administration for the treatment of smallpox. The drug impedes the spread of virus in the body by preventing virus particles from exiting human cells. The drug targets a protein that is found on both the virus that causes smallpox and the monkeypox virus.

"Monkeypox has caused a high burden of disease and death in children and adults in the Democratic Republic of the Congo, and improved treatment options are urgently needed," said NIAID Director Anthony S. Fauci, MD. "This clinical trial will yield critical information about the safety and efficacy of tecovirimat for monkeypox. I want to thank our DRC scientific partners as well as the Congolese people for their continued collaboration in advancing this important clinical research."

Since the 1970s, monkeypox virus has caused sporadic cases and outbreaks, primarily in the rainforest areas of central Africa, and in west Africa. A multi-continent outbreak of monkeypox in areas where the disease is not endemic, including Europe and the United States, has been ongoing since May 2022 with the majority of cases occurring in men who have sex with men. The outbreak has prompted recent public health emergency declarations from the WHO and the U.S. Department of Health and Human Services. From Jan.1, 2022 to Oct. 5, 2022, the WHO has reported 68,900 confirmed cases and 25 deaths from 106 countries, areas and territories.

According to the WHO, cases identified as part of the ongoing global outbreak are largely caused by monkeypox virus Clade IIb. Clade I, which is estimated to cause more severe disease and higher mortality than Clade IIa and Clade IIb, especially in children, is responsible for infections in the DRC. The Africa Centres for Disease Control and Prevention (Africa CDC) has reported 3,326 cases of monkeypox (165 confirmed; 3,161 suspected) and 120 deaths in the DRC from Jan. 1, 2022 to Sept. 21, 2022.

People can become infected with monkeypox through contact with infected animals, such as rodents, or nonhuman primates or humans. The virus can transmit among humans by direct contact with skin lesions, body fluids, and respiratory droplets, including through intimate and sexual contact; and by indirect contact with contaminated clothing or bedding. Monkeypox can cause flu-like symptoms and painful skin lesions. Complications can include dehydration, bacterial infections, pneumonia, brain inflammation, sepsis, eye infections and death.

The trial will enroll up to 450 adults and children with laboratory-confirmed monkeypox infection who weigh at least 3 kilograms. Pregnant women are also eligible to enroll. The volunteer participants will be assigned at random to receive either oral tecovirimat or placebo capsules twice daily for 14 days, with the dose administered dependent on the participant's weight. The trial is double-blinded, so participants and investigators do not know who will receive tecovirimat or placebo.

All participants will stay at a hospital for at least 14 days where they will receive supportive care. Study clinicians will regularly monitor participants' clinical status throughout the study, and participants will be asked to provide blood, throat swab, and skin lesion swab samples for laboratory evaluations. The study is primarily designed to compare the average time to healed skin lesions among those receiving tecovirimat versus those receiving placebo. Investigators will also gather data on multiple secondary objectives, including comparisons of how quickly participants test negative for monkeypox virus in the blood, overall severity and duration of disease, and mortality between groups.

Participants will be discharged from the hospital once all lesions have scabbed over or flaked off, and after they test negative for monkeypox virus in the blood for two days in a row. They will be followed for at least 28 days and will be asked to return for an optional study visit after 58 days for additional clinical and laboratory tests. An independent Data and Safety Monitoring Board will monitor participant safety throughout the duration of the study.

The trial is led by co-principal investigators Jean-Jacques Muyembe-Tamfum, MD, PhD, director-general of INRB and professor of microbiology at Kinshasa University Medical School in Gombe, Kinshasa; and Placide Mbala, MD, PhD, operations manager of the PALM project and head of the Epidemiology Department and the Pathogen Genomic Laboratory at INRB.

"I am happy that monkeypox is no longer a neglected disease and that soon, thanks to this study, we will be able to prove that there is an effective treatment for this disease," said Dr. Muyembe-Tamfum.

For more information, please visit clinicaltrials.gov and search identifier NCT05559099. The trial timeline will depend on the pace of enrollment. A separate NIAID-supported trial of TPOXX is ongoing in the United States. For information about the U.S. trial, visit the AIDS Clinical Trials Group (ACTG) website and search TPOXX or study A5418.

PALM is short for “Pamoja Tulinde Maisha” a Kiswahili phrase that translates to “together save lives.” NIAID and the DRC Ministry of Health established the PALM clinical research partnership in response to the 2018 Ebola outbreak in Eastern DRC. The collaboration has continued as a multilateral clinical research program composed of NIAID, the DRC Ministry of Health, INRB and INRB’s partners. PALM’s first study was the randomized controlled trial of multiple therapeutics for Ebola virus disease, which supported the regulatory approvals of the NIAID-developed mAb114 (Ebanga) and REGN-EB3 (Inmazeb, developed by Regeneron) treatments.

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http://beta.docker.poz.com/article/monkeypox-treatment-trial-begins-democratic-republic-congo