The STOMP Trial Evaluates an Antiviral for Mpox [VIDEO]

Mpox (formerly monkeypox) remains a health threat, and no treatment has been proven safe and effective.

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Following a peak in the summer of 2022, new infections in the mpox clade IIb outbreak have decreased, due in part to the rapid availability and uptake of vaccines and other preventive measures. However, mpox remains a health threat, and no treatment has been proven safe and effective for people experiencing mpox disease.

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, launched the STOMP trial to determine whether the antiviral drug tecovirimat can safely and effectively treat mpox. Tecovirimat, also known as TPOXX, was initially developed and approved by the Food and Drug Administration to treat smallpox—a species of virus closely related to mpox—but the drug's safety and efficacy as an mpox treatment has not been established.

The STOMP trial is a Phase 3 study that aims to enroll about 500 people—a process that may require considerable time while mpox burden is low in study countries. NIAID continues to prioritize this study even while case counts are low.

VIDEO: Cyrus Javan of NIAID's Division of AIDS explains the importance of the STOMP trial.

The STOMP trial was designed to be as inclusive as possible to ensure study results provide information on how tecovirimat works in the diverse populations affected by mpox. The trial is enrolling adults and children of all races and sexes, people with HIV, and pregnant and lactating people across 60 sites in the United States and Mexico, with an option for remote enrollment from other U.S. locations. More sites are expected to open in East Asia and South America.

The mpox virus has been endemic—occurring regularly—in west, central and east Africa since the first case of human mpox disease was identified in 1970. Mpox can cause flu-like symptoms and painful blisters or sores on the skin. People who acquire mpox tend to clear the infection on their own, but the virus can cause serious disease in children, pregnant people, and other people with compromised immune systems, including individuals with advanced HIV disease. Rare but serious complications of mpox include dehydration, bacterial infections, pneumonia, brain inflammation, sepsis, eye infections and death.

Completing the STOMP trial is essential, not only to evaluate a therapeutic option for the current mpox outbreak, but also to guide preparation for future outbreaks and provide evidence that could inform medical practice in historically endemic countries. The STOMP trial is sponsored by NIAID and led by the NIAID-funded AIDS Clinical Trials Group.

Beyond STOMP, NIAID is co-sponsoring the PALM007 trial of tecovirimat as treatment for clade I mpox in the Democratic Republic of the Congo (DRC) with the DRC's National Institute of Biomedical Research. PALM007 is actively enrolling. In addition, NIAID is sponsoring an immunogenicity study of the Jynneos preventive vaccine, which has completed enrollment and is expected to report initial results in 2024. More information about these studies, including enrollment in STOMP and PALM007, is available here:

STOMP tecovirimat treatment study
PALM007 tecovirimat treatment study
Jynneos vaccine study

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