

# Study of Tecovirimat for Human Monkeypox Virus

**Status:** Recruiting

## Eligibility Criteria

**Age:** Not specified

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

Inclusion Criteria (All participants; Arms A, B, and C): 1. Laboratory-confirmed or presumptive HMPXV infection. 2. HMPXV illness of <14 days duration immediately prior to study entry. 3. At least one active (not yet scabbed) skin lesion, mouth lesion, or proctitis with or without visible ulcers. 4. Non-pregnant people of reproductive potential must agree to use at least one effective means of contraception when engaging in sexual activities that can result in pregnancy, from the time of enrollment through the end of study participation. Additional Inclusion Criteria for Arms A and B: 1. Age  $\geq 18$  years at the time of study entry Additional Inclusion Criteria for Arm C; Participants who meet the above entry criteria who also meet any of the following criteria will be registered to Arm C: 1. Participants age <18 years at the time of study entry 2. Those with severe HMPXV disease Those with or without severe disease and with one or more of the following will also be enrolled into Arm C:

- Severe immunosuppression

- Skin conditions placing the person at higher risk for disseminated infection Exclusion Criteria (All participants; Arms A, B, and C): 1. Prior or concomitant receipt of tecovirimat (e.g., under an alternative access mechanism. 2. Planned initiation of intramuscular cabotegravir/rilpivirine during study drug administration or for two weeks following completion of study drug administration. Participants who are stable on long-acting intramuscular cabotegravir/rilpivirine may enroll. 3. Participants who, in the judgement of the investigator, will be at significantly increased risk as a result of participation in the study. 4. Participants who require intravenous dosing of tecovirimat.

## Conditions & Interventions

**Interventions:**

Drug: Tecovirimat Oral Capsule, Drug: Placebo, Drug: Tecovirimat Oral Capsule (Open Label)

**Conditions:**

Monkeypox

**Keywords:**

HMPXV

## More Information

**Contact(s):** ACTG Clinicaltrials.gov Coordinator - ACTGCT.gov@fstf.org

**Principal Investigator:**

**Phase:** Phase 3

**IRB**

**Number:**

**System ID:** NCT05534984

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