Implementation Study of Lenacapavir Pre-exposure Prophylaxis for HIV Prevention

NCT07473778

Status RECRUITING
Sponsor Gilead Sciences
Enrollment 3,000 participants

Key Eligibility Criteria

Inclusion (7)

- Able to comprehend and provide a signed written informed consent, which must be obtained prior to initiation of screening study procedures;
- Willing and able to comply with all study requirements;
- Presents at a study site needing or wanting PrEP for HIV prevention as determined by local clinical practice guidelines and institutional protocols, including new PrEP users (PrEP naïve) and current or former users of oral (emtricitabine/tenofovir disoproxil fumarate (coformulated; Truvada®; F/TDF) or emtricitabine/tenofovir alafenamide (coformulated; Descovy®; F/TAF)) or injectable (LEN or cabotegravir (CAB)) PrEP who indicate interest in discussing PrEP methods that they are clinically eligible to receive;
- Eligible for LEN PrEP per standard of care procedures, for example, being HIV-1 negative at screening using a Food and Drug Administration (FDA) approved/cleared test for diagnosis of acute or primary HIV-1 infection;
- After PrEP counseling to learn about the advantages and disadvantages of various PrEP methods:

... and 2 more (see full listing online)

Exclusion (1)

- Any other indication not already listed above that would make the participant ineligible for LEN PrEP at enrollment according to local guidelines, organizational protocols, US Prescribing Information (USPI) for the PrEP product, and/or Center for Disease and Control (CDC) guidance.

Locations (4 total)

Bliss Health, Orlando, Florida, United States
Faebris Medical & Community Education, Atlanta, Georgia, United States
Be Well Medical Center, Berkley, Michigan, United States
... and 1 more locations