MedicalXpress

NIH launches first large trial of a long-acting injectable drug for HIV prevention

December 20 2016

The first large-scale clinical trial of a long-acting injectable drug for HIV prevention began today. The study, sponsored by the National Institutes of Health, will examine whether a long-acting form of the investigational anti-HIV drug cabotegravir injected once every 8 weeks can safely protect men and transgender women from HIV infection at least as well as the anti-HIV medication Truvada taken daily as an oral tablet. If injectable cabotegravir is found to be effective for HIV pre-exposure prophylaxis, also known as PrEP, it may be easier for some people to adhere to than daily oral Truvada, the only licensed PrEP regimen. Truvada consists of the two anti-HIV drugs emtricitabine and tenofovir disoproxil fumarate.

"We urgently need more HIV prevention tools that fit easily into people's lives," said Anthony S. Fauci, M.D., director of the National Institute of Allergy and Infectious Diseases (NIAID), part of NIH. "Although daily oral Truvada clearly works for HIV prevention, taking a daily pill while feeling healthy can be difficult for some people. If proven effective, injectable cabotegravir has the potential to become an acceptable, discreet and convenient alternative for HIV prevention."

NIAID is collaborating on the Phase 3 clinical trial of injectable cabotegravir with ViiV Healthcare, Gilead Sciences, Inc., and the NIH-funded HIV Prevention Trials Network (HPTN). In a novel funding structure for an NIH HIV prevention study, NIAID and ViiV Healthcare are co-funding the trial. NIAID is sponsoring the study, called HPTN 083, and ViiV Healthcare and Gilead Sciences are providing the study

medications.

The study will enroll 4,500 men who have sex with men and transgender women who have sex with men at 45 sites in eight countries in the Americas, Asia and Africa. Participants will be aged 18 years or older and at high risk for HIV infection. Results are expected in 2021.

"The annual number of new HIV infections among young people, especially young men who have sex with men and transgender women who have sex with men, has been on the rise despite nearly flat HIV incidence among adults worldwide," said HPTN 083 Protocol Chair Raphael J. Landovitz, M.D., M.Sc. "It is essential to develop multiple effective HIV prevention modalities so the most vulnerable populations have a choice of preventive options. We hope injectable cabotegravir will become one such modality." Dr. Landovitz is an associate professor of medicine at the David Geffen School of Medicine at University of California, Los Angeles, and associate director of the UCLA Center for Clinical AIDS Research & Education.

HPTN 083 study participants will be randomly assigned to either the cabotegravir group or the Truvada group. Neither the participants nor the study team will know who is in which group until the end of the trial.

Participants will be in the study for an average of 4.5 years. During their first five weeks after enrollment, they will receive two daily oral tablets: either cabotegravir or Truvada, and a placebo pill. Beginning in the sixth week, participants in the cabotegravir group will receive injections of cabotegravir and placebo tablets to be taken orally daily, while participants in the Truvada group will receive placebo injections and Truvada tablets to be taken orally daily. Injections will be administered by study staff. The first two injections will be four weeks apart, then once every 8 weeks for an average of nearly 3.5 years. After completing the injections, all participants will be offered 48 weeks of PrEP with

daily oral Truvada.

HPTN 083 study participants will receive HIV prevention counseling, condoms and lubricant, as well as counseling to encourage and support adherence to the daily oral pill. Participants will be tested for sexually transmitted infections (STIs) throughout the study and referred for appropriate treatment if an STI is diagnosed. Study participants who become HIV-infected during the trial will stop receiving the study products and be referred to local medical providers for HIV care and treatment.

"The HPTN 083 study has the potential to provide game changing data as the first large-scale test of a long-acting injectable drug for HIV prevention," said Protocol Co-Chair Beatriz Grinsztejn, M.D., Ph.D. Dr. Grinsztejn directs the Instituto de Pesquisa Clinica Evandro Chagas HIV/AIDS Clinical Research Centre of the Oswaldo Cruz Foundation-Fiocruz in Rio de Janeiro, Brazil.

A related study called HPTN 084 will test the safety and efficacy of injectable cabotegravir for HIV prevention in young women in sub-Saharan Africa beginning in 2017. This study will be supported by NIAID, the U.S. Agency for International Development and ViiV Healthcare.

Provided by NIH/National Institute of Allergy and Infectious Diseases