Major Trial of Long-Acting Injectable PrEP Launches Among African Women

A trial of long-acting cabotegravir injected every eight weeks is already under way among men who have sex with men and trans women.

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A large-scale trial of long-acting injectable cabotegravir as pre-exposure prophylaxis (PrEP) given every eight weeks has launched among sexually active HIV-negative women in Africa. Known as HPTN 084, this trial follows the launch a year ago of a similar study of long-acting cabotegravir among transgender women and cisgender men who have sex with men (MSM) called HPTN 083.

The Phase III HPTN 084 study is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), a division of the National Institutes of Health (NIH) in partnership with ViiV Healthcare and the Bill & Melinda Gates Foundation.

The new trial is set to enroll about 3,200 women between 18 and 45 years old at 20 sites in seven nations in southern and eastern Africa. The participants will be randomized to two arms: the long-acting cabotegravir arm or the Truvada (tenofovir disoproxil fumarate/emtricitabine) as PrEP arm. The study is double blinded, so neither the investigators nor the participants will know to which arm participants, who will remain in the study for an average of 3.6 years, have been assigned.

For the first five weeks, the women will be instructed to take two tablets daily—one will be a placebo and the other either oral cabotegravir or Truvada. Then the participants will begin receiving injections (administered by the study staff) of either long-acting cabotegravir or, for those in the Truvada arm, a placebo. During the same period, they will receive daily tablets that will be either Truvada or, for those in the cabotegravir arm, a placebo. The first two injections will be spaced four weeks apart; thereafter, the injections will be given every eight weeks for an average of 2.6 years.

After completing the injection phase of the study, the participants will be offered 48 weeks of daily Truvada as PrEP. This phase of the study is to compensate for the long “tail” of long-acting cabotegravir; research indicates that long-acting cabotegravir may linger in the body for up to a year following a final injection. Daily Truvada, therefore, may prevent the development of HIV drug resistance facilitated by levels of cabotegravir low enough to fail in preventing acquisition of the virus but high enough to spur resistance.

The results of HPTN 084 are expected in 2022. Results for HPTN 083 are expected in late 2021 or early 2022.

To read a press release about HPNT 084, click here.
