# Trial Will Assess HIV-Preventing Vaginal Ring and PrEP in Pregnant Women

The safety trial will enroll pregnant women in several sub-Saharan African nations.

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A clinical trial funded by the National Institutes of Health (NIH) will assess the safety of the HIV-preventing monthly vaginal ring as well as daily oral Truvada as pre-exposure prophylaxis (PrEP) among pregnant women in sub-Saharan Africa. The study will also examine how well the women accept these proven prevention methods.

Research has indicated that Truvada (tenofovir disoproxil fumarate/emtricitabine) as PrEP is associated with a 90% or greater reduction in the risk of HIV among cisgender women. Use of the monthly vaginal ring, which is infused with the antiretroviral dapivirine, is associated with an approximate overall reduction in HIV risk of 30% in populations of women received the ring in clinical trials.

Truvada as PrEP and the tablet's generic equivalent are increasingly available around the world, while the vaginal ring is poised for an approval decision from the European Medicines Agency for its potential use in sub-Saharan Africa.

"Women need reliable HIV prevention methods that they know are safe during pregnancy for themselves and their babies," Anthony S. Fauci, MD, the director of the National Institute of Allergy and Infectious Diseases, which is part of the NIH, said in a press release. "This new clinical trial will provide important data on the safety of PrEP and the dapivirine ring during pregnancy and will help expectant parents make well-informed HIV prevention choices."

The Phase III DELIVER study, also called MTN-042, will enroll 750 healthy HIV-negative women 18 to 40 years old who have an uncomplicated pregnancy with a single fetus. The women will be randomly assigned 2 to 1 to receive either the vaginal ring or Truvada as PrEP and will be asked to use their assigned form of HIV prevention through the end of their pregnancy or 42 weeks of gestation, whichever comes first.

The mothers will be followed for approximately six weeks after delivery. After the infants are born, they will also be enrolled in the study and followed through 12 months of age.

The study has a particularly cautious design. The women will be enrolled in four stages, starting

with an initial group of 150 women who will be assigned to receive PrEP or the vaginal ring at 36 to 37 weeks of gestation. Once these women have been followed for a substantial amount of time, an independent panel of experts will determine whether safety data indicate that a subsequent group of women can be enrolled or whether the study should be terminated.

This cycle of enrollment and independent safety assessment is slated to be repeated with a series of groups of 150 women enrolled at 30 to 35 weeks of gestation, 150 women at 20 to 29 weeks of gestation and finally 300 women at 12 to 19 weeks of gestation.

Meanwhile, another NIH-funded trial, IMPAACT 2009, which began in early 2019, has been assessing whether Truvada as PrEP drug concentrations in HIV-negative adolescents and young women 16 to 24 years old are different during pregnancy compared with other times. The trial, conducted in southern and eastern Africa, is gearing up to begin testing the safety, acceptability and efficacy of PrEP drugs during pregnancy and the first six months after birth. It is expected to produce results in 2022.

Yet another NIH-funded clinical trial, B-PROTECTED, is expected to begin in the coming months and will assess the safety of Truvada as PrEP and the dapivirine ring in HIV-negative breast-feeding women and their infants. Also called MTN-043, this trial will enroll 200 women and their 6- to 12-week-old infants in Malawi, South Africa, Uganda and Zimbabwe.

To read a press release about the DELIVER trial, click here.

For more information on the trial, visit ClinicalTrials.gov, trial number NCT03965923.

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