

Vaginal Ring for HIV Prevention Shows Promise in U.S. Adolescents

A recent study found that the antiretroviral-containing ring was safe and that the girls in the trial used it well.

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A recent study of an HIV-preventing vaginal ring among teenage girls in the United States found that this female-centric form of pre-exposure prophylaxis (PrEP) was safe and that the girls used it well. This study was the first to test the ring among females younger than 18.

Findings from the MTN-023/IPM 030 study, which enrolled 96 girls between ages 15 and 17 in six U.S. cities from July 2014 to July 2016, were presented at the 9th International AIDS Society Conference on HIV Science in Paris (IAS 2017)

Previously, a pair of Phase III trials, called [ASPIRE](#) and [The Ring Study](#), showed that the ring, which contains the antiretroviral (ARV) dapivirine, was safe and reduced the risk of HIV acquisition among African women 18 to 45 years old. The International Partnership for Microbicides (IPM), one of the agencies behind this research, is seeking regulatory approval for the ring as a form of PrEP among women in this age range.

The MTN-023/IPM 030 was designed to provide the necessary data to expand such an approval for younger females. The National Institutes of Health (NIH)-funded Microbicide Trials Network (MTN) is running the trial in partnership with the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN).

The study randomized the participants so that 73 received the dapivirine-containing ring and 23 received a placebo ring. The study investigators asked the girls to use each of the rings they received for a month at a stretch before switching to a new one for a total of six months.

There were no differences in the safety of either the drug-containing ring or the placebo.

Promisingly, the participants adhered well to the ring regimen (in stark contrast with the women in the African trials). According to the participants' reports, 42 percent of the U.S. women didn't remove their rings except to swap them out at the end of each month. Among those who received the dapivirine-containing ring, 87 percent had detectable levels of drug in their blood samples, suggesting that they had at least used the ring the previous day. Of the rings the women returned

to the investigators, 95 percent had remaining drug levels that suggested they were used consistently during the previous month.

At the three- and six-month points in the study, 93 percent of the participants reported they liked the ring. Ninety-five percent of them said the ring was easy to use. Seventy-four percent reported they were not even aware of the ring as they carried out their everyday activities, although some expressed concern that their sexual partners would sense the ring during intercourse.

Overall, the women in the two African studies of the ring did not use the ring well. In ASPIRE, the women saw an overall 27 percent HIV risk reduction, according to data [presented](#) at the 2016 Conference on Retroviruses and Opportunistic Infections (CROI) in Boston. However, a subsequent analysis [reported](#) at the 21st International AIDS Conference in Durban, South Africa, (AIDS 2016) showed that those who used the ring consistently reduced their risk of infection by at least 56 percent; those who had near-perfect use benefited from as much as a 75 percent risk reduction.

The Microbicide Trials Network, which also sponsored ASPIRE, intends to begin a second trial, known as REACH, that will analyze the safety of the ring among 300 16- to 21-year-old females in sub-Saharan Africa. The study, which researchers hope will begin in late 2017, will compare the safety and efficacy of the ring with daily Truvada (tenofovir disoproxil fumarate/emtricitabine) as PrEP. The study will also examine whether biological or physiological factors—for example, [differing dominant bacterial populations, or microbiomes, in the vagina](#)—affect the efficacy of the ring. REACH, which is also known as MTN-032/IPM 045, will also look at the preferences of the participants when it comes to the ring versus daily oral PrEP.