Vaginal Ring and Truvada Safe for HIV Prevention During Late Pregnancy

Little HIV prevention research has included pregnant women for fear of adverse birth outcomes.

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Women who start taking oral Truvada (tenofovir disoproxil fumarate/emtricitabine) or use the dapivirine vaginal ring to protect themselves from HIV acquisition through vaginal sex at the end of their pregnancies saw almost no safety concerns—for themselves or their babies, according to interim data from the DELIVER trial presented at the 11th International AIDS Society Conference of HIV Science (IAS 2021).

This is important because studies of HIV treatment or pre-exposure prophylaxis (PrEP) methods generally exclude pregnant women for fear of exposing the fetus to potentially harmful side effects. That's why almost no research has been done about which medications for HIV treatment or prevention are best during pregnancy before the drugs have been approved for everyone else. And it's also why, when the Food and Drug Administration approved Descovy (tenofovir alafenamide/emtricitabine) for PrEP, it didn't do so for people exposed via vaginal sex—the research just isn't there.

The interim data was the first to come from the Phase III DELIVER clinical trial, which compared the safety of the dapivirine vaginal ring and oral Truvada for the prevention of HIV in women during pregnancy. The first cohort of 150 women, whose data this analysis was based on, were near the end of their pregnancies, with at least 36 weeks gestation. The participants were randomized two to one to use either the dapivirine vaginal ring or daily oral PrEP. The researchers followed the women for six weeks and measured biomarkers of safety and effectiveness, both for the women and their babies.

If the two prevention options continue to be safe, researchers will enroll another 150 women who are between 30 and 35 weeks pregnant in the same design. If that cohort proves safe, they will enroll a final group of 250 women who are the earliest in their pregnancy, between 12 to 29 weeks of gestation. The study was originally going to enroll 750 people in four arms, but the protocol team revised the design in May 2021 to support regulatory approval of the rings in several African countries this year and reduced the total number of participants from 750 total to 550.

Researchers didn't expect to see many side effects late in pregnancy, according to an interview with researcher Katherine Bunge, MD, of the University of Pittsburgh in 2018. She told

TheBodyPRO that they were “starting with the lowest-risk pregnancy group.”

“When someone’s 36 weeks [pregnant], the baby is pretty well developed,” she said at the time. “The bulk of our safety data” would come from cohorts not yet enrolled in the trial—especially those enrolled at 12 to 19 weeks gestation. This is because “we will have the most women for the longest time of exposure. We don’t just want to jump in and do it with those women because we want to make sure it’s safe first.”

So these interim data held few surprises. One infant was stillborn in the oral PrEP arm, but that was determined to be unrelated to the study drugs. All the other babies were born alive, and all but three at full term. One of the preterm births was in the vaginal ring arm and two were in the oral PrEP arm. Pregnancy complications were rare. None of those were deemed related to either the dapivirine ring or oral PrEP.

On the maternal side, women reported a total of eight adverse events in the dapivirine ring arm and 10 in the oral PrEP arm. The most common one was gestational hypertension, which occurred in three women using dapivirine rings and four women on oral PrEP. However, none of these were deemed related to either HIV prevention method. There were also four cases of hemorrhage—two in the postpartum period in the dapivirine ring group, one before or during childbirth in the oral PrEP arm and one postpartum in the oral PrEP group. Again, none of these were related to the study method. There was only one instance of a severe adverse event related to study drugs—severe nausea in a woman taking oral PrEP.

“In this first study of a long-acting HIV prevention agent in pregnancy, adverse pregnancy outcomes and complications were uncommon when the [dapivirine vaginal ring] and [tenofovir] were used late in pregnancy and were generally similar to rates observed in the communities where the study is being conducted,” wrote Bonus Makanani, MBBS, of the Malawi College of Medicine–Johns Hopkins University Research Project, and colleagues in their poster. “These data support plans for subsequent investigation of safety among pregnant women using [the dapivirine vaginal ring] earlier in pregnancy.”

In shocking news, Makanani passed away directly before the IAS meeting, causing the research team to pull back from promoting the data, Lisa Rossi, the press person for the Microbicide Trials Network (MTN), which conducted the study, told POZ.

In a letter to the greater MTN community, MTN leader Sharon Hillier, PhD, of the University of Pittsburgh, recalled meeting Makanani at Queen Elizabeth Hospital in Blantyre, Malawi, where he was an obstetrician and gynecologist. He was also an investigator in earlier trials of the dapivirine ring, ASPIRE and HOPE.

“I last spoke to Bonus about three weeks ago, when he told me how thrilled he was that this study evaluating the safety of the dapivirine ring and Truvada as oral PrEP had completed the first cohort of pregnant women,” Hillier wrote. “It is nearly impossible to express my sorrow and loss of someone who I considered to be both a friend and a brother. He was deeply loved by everyone at the Blantyre CRS, by his many colleagues at Malawi College of Medicine, Queen Elizabeth Hospital

and Johns Hopkins University—and by all of us at the MTN. We can only rejoice in the fact that he shared so much with us and that he made such a profound impact on his community and our world. He was the best of humankind, and we will miss him."

In other MTN news, researchers also presented data showing for the first time that adolescent girls and young women at high risk for HIV can successfully use PrEP, either as the vaginal ring or Truvada. The trial of 247 girls and young women ages 16 to 21 found that 54% of participants overall used their HIV prevention method as prescribed. This rate was slightly lower, 50%, in the ring arm and slightly higher, 59%, in the oral PrEP arm. This confirms other research showing that teens and young women are less adherent to HIV prevention methods than older adults.

Click here to read the first study abstract.

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