STI Rate Did Not Rise During Descovy Versus Truvada PrEP Trial

The study's authors saw no evidence that the participants increased their sexual risk taking during the 96-week trial.

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Participants in the major clinical trial that compared Descovy (tenofovir alafenamide/emtricitabine) versus Truvada (tenofovir disoproxil fumarate/emtricitabine) as pre-exposure prophylaxis (PrEP) did not experience a rise in their sexually transmitted infection (STI) diagnosis rate over a two-year period.

The DISCOVER trial's authors saw no evidence that its participants increased their rate of sex that poses a risk of STI or HIV transmission during the study, according to a presentation at the International AIDS Conference, which was held virtually last week.

That said, the STI diagnosis rate remained high among the transgender women and men who have sex with men who participated in the trial.

DISCOVER's efficacy findings, which were first presented in March 2019, supported the approval of Descovy as PrEPfor certain people in October, after the combination tablet was found to be as effective at preventing HIV acquisition as Truvada.

The trial randomized 5,399 people into two even groups to receive either daily Descovy or Truvada as PrEP on a blinded basis, meaning no one knew which drug they were receiving. Eighty-one percent of the Descovy group and 82% of the Truvada group stayed in the study over time.

Upon entering the study, 10% of those in the Descovy group and 10% of those in the Truvada group had been diagnosed with rectal gonorrhea in the past 24 weeks. A respective 13% and 12% had been diagnosed with rectal chlamydia during that time frame, and a respective 9% and 10% had been diagnosed with syphilis during that period.

Rectal STI infections and syphilis are considered a sign that an individual is at high risk of contracting HIV without the use of PrEP.

STI testing conducted at the study's baseline indicated that 16.1% of those in the Descovy arm and 15.8% in the Truvada arm had gonorrhea or chlamydia at any site (rectal, genital or throat). A

respective 11.3% and 10.5% tested positive for gonorrhea or chlamydia in the rectum.

The study ran for 96 weeks, after which point the participants were told which form of PrEP they had received and were offered Descovy on an unblinded basis for an additional 48 weeks.

Through week 96, the rate of STI diagnoses per cumulative years of follow-up was 86 diagnoses of gonorrhea or chlamydia in the Descovy group and 83 such diagnoses in the Truvada arm, including a respective 21 and 20 diagnoses of rectal gonorrhea and 27 diagnoses of rectal chlamydia in each group.

For each 100 cumulative years of follow-up through week 96, there were 0.16 HIV diagnoses among those who received Descovy and 0.30 diagnoses among those who received Truvada. The difference between these diagnosis rates was not statistically significant, meaning it could have been driven by chance. Consequently, the study's authors concluded that Descovy and Truvada are comparably effective as PrEP.

The proportion of study participants diagnosed with gonorrhea or chlamydia at each study visit—visits occurred every 12 weeks—declined from the baseline rate by 9.9% per year. The proportion diagnosed with rectal gonorrhea or chlamydia at each study visit declined by 11.3% per year.

Upon entering the study, the participants reported a median of 3.5 recent sexual partners with whom they had had condomless receptive anal sex, compared with a median of 3.9 reported recent partners at week 96. The difference between these figures was not statistically significant, meaning it could have been driven by chance.

Those who had a history of rectal gonorrhea, rectal chlamydia or syphilis upon entering the study were diagnosed with HIV at a rate of 0.57 diagnoses per 100 cumulative years of follow-up compared with a rate of 0.11 diagnoses among those who did not have such a history at the study's baseline.

The STI diagnosis rate per 100 cumulative years of follow-up during the study was 118 gonorrhea diagnoses among the 23 people diagnosed with HIV compared with a rate of 44 among those who were not diagnosed with HIV. Those diagnosed and not diagnosed with HIV had 56 and 20 cases of rectal gonorrhea, respectively, 113 and 40 cases of chlamydia, 72 and 27 cases of rectal chlamydia and 31 and 10 cases of syphilis. All these differences were statistically significant.

The study authors concluded that STI diagnosis rates remained high during the 96-week DISCOVER trial but that the proportion of participants diagnosed with an STI at each study visit decreased slightly over time. Those who acquired HIV during the study had a higher rate of STI diagnosis during the study as well as a higher historical STI diagnosis rate upon entering the trial. Also, in combination with the participants' reports of their sexual behavior, the study's data indicated that the DISCOVER participants did not increase their rate of sex that poses a risk of STIs or, in the absence of daily PrEP, HIV transmission.

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