Adding Bictegravir to Descovy Could Simplify PEP and On-Demand PrEP in Monkeys

Researchers are looking for ways to reduce the doses needed for on-demand PrEP and the 30-day duration recommended for PEP.

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Searching for a way to simplify the dosing requirements for on-demand pre-exposure prophylaxis (PrEP) as well as the length of time required to complete post-exposure prophylaxis (PEP), researchers conducting research in monkeys have found that adding the integrase inhibitor bictegravir to Descovy (tenofovir alafenamide/emtricitabine) showed promise in addressing both of these needs.

Descovy is approved for use as daily PrEP but not for people who have vaginal sex. Only Truvada (tenofovir disoproxil fumarate/emtricitabine) has been vetted through research for use as an on-demand form of PrEP and only among men who have sex with men.

To follow that regimen, men should take two tablets of Truvada two to 24 hours before expected intercourse and then, if intercourse occurs, one dose 24 hours after the initial double dose and then one last dose 24 hours after that. Studies have found that this strategy offers a high level of protection against HIV.

PEP should be initiated within 48 to 72 hours after a presumed exposure to HIV. In this case, individuals receive a three-drug antiretroviral regimen for 30 days.

Elena Bekerman, PhD, of Gilead Sciences, which manufactures bictegravir, Descovy and Truvada, presented findings from the new monkey study at the 2020 Conference on Retroviruses and Opportunistic Infections in Boston last week.

First, the researchers conducted experiments in which they analyzed the metabolism of various doses of bictegravir along with the standard dose of Descovy in Indian rhesus macaque monkeys. This led them to select a 25 milligram dose of bictegravir for what they called Study 1.

In this study, 41 monkeys received six to eight rectal exposures of SHIV, a hybrid simian-human version of HIV engineered for research purposes, spaced two weeks apart.

The animals were divided into seven groups. Six monkeys received a placebo. Twelve animals received on-demand PrEP, including one dose of either Descovy (six monkeys) or bictegravir plus Descovy (six monkeys) two hours prior to the SHIV exposure and a second dose of their assigned regimen 24 hours after the exposure.

Twelve animals received one dose of PEP 24 hours after the SHIV exposure and a second dose 48 hours after the exposure; six of them received Descovy and six received bictegravir plus Descovy. Another 11 animals also received PEP, except these received their doses 48 hours and 72 hours after exposure, respectively; five received Descovy, and six received bictegravir plus Descovy.

In the PrEP group, all the placebo monkeys were infected with SHIV after three challenges, compared with just one of the monkeys in the Descovy group and none in the bictegravir plus Descovy group. This meant that Descovy was associated with a 95% reduction in SHIV risk and bictegravir plus Descovy was associated with a 100% reduction in risk. These risk reductions were statistically significant, meaning they are unlikely to have been driven by chance.

None of the animals in the PEP groups benefited from a statistically significant reduction in SHIV risk, meaning that any apparent reduction they did receive may have been the result of chance. Among those that received doses 24 hours and 48 hours after the SHIV challenge, five out of six that received Descovy and the same proportion that received bictegravir plus Descovy were infected. Among the monkeys that received doses of PEP 48 hours and 72 hours after the SHIV challenge, all were infected with SHIV regardless of the regimen.

The study authors observed a trend that suggested that adding 25 of bictegravir to Descovy offered a protective benefit against SHIV.

Next, the investigators conducted what they called Study 2, in which they increased the bictegravir dose to 100 mg and tested a number of ways of timing PEP among seven groups of six monkeys each.

One group received a placebo. Twelve animals received PEP six hours and 30 hours after exposure to SHIV, respectively, with six receiving Descovy and six receiving bictegravir plus Descovy. Twelve animals received PEP 12 hours and 30 hours after SHIV exposures, respectively, with six receiving Descovy and six receiving bictegravir plus Descovy. Six monkeys received bictegravir plus Descovy 24 hours and 48 hours after the SHIV exposure and another six received the regimen 48 hours and 72 hours after exposure to the virus.

The monkeys in Study 2 all received eight rectal SHIV exposures spaced two weeks apart.

Five out of six of the monkeys in the placebo group contracted SHIV. In the group that received PEP six hours and 30 hours after the SHIV exposure, three of those that received Descovy and one of those that received bictegravir plus Descovy contracted SHIV. This meant that 100 mg of bictegravir plus Descovy was associated with a statistically significant 90% reduction in risk, while Descovy did not significantly reduce risk.

In the group that received PEP 12 and 36 hours after exposure to SHIV, two members of each treatment group contracted SHIV, although this occurred after far more exposure to the virus among those that received bictegravir plus Descovy compared with those that received Descovy. This meant that only 100 mg of bictegravir plus Descovy significantly reduced the risk of SHIV—by 82%.

Two SHIV infections occurred in each of the two groups that received bictegravir plus Descovy either 24 hours and 48 hours after exposure or 48 hours and 72 hours after exposure. In neither case was the regimen associated with a significant reduction in SHIV risk.

The study authors concluded that simplified two-dose schedules of both on-demand PrEP and PEP can protect macaques against SHIV infections. Descovy was protective as on-demand PrEP only when given two hours before and 24 hours after exposure to SHIV. Twenty-five milligrams of bictegravir plus Desocvy was protective as on-demand PrEP initiated two hours prior to exposure to the virus. One hundred milligrams of bictegravir plus Descovy was effective as PEP initiated up to 12 hours after exposure to the virus.

Gilead researchers plan to conduct further research to more precisely define the optimal on-demand PrEP and PEP dosing schedules in both rectal and vaginal exposure monkey models.

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