Clinical Trials for HIV Meds Under-Recruit Women and People of Color

Researchers compared the demographics of participants in randomized controlled trials for antiretrovirals with the global HIV population.

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Compared with the race- and sex-based demographics of the global HIV population, participants of randomized controlled trials for major antiretrovirals (ARVs) are less likely to be women and people of color.

Publishing their findings in the Journal of Virus Eradication, researchers compared the demographics of participants in Phase III randomized controlled trials of three widely prescribed ARVs, dolutegravir, bictegravir, tenofovir alafenamide (TAF) and doravirine, with those of the global HIV population.

The investigators drew sex-based data on national HIV epidemics from a 2018 Joint United Nations Programme on HIV/AIDS (UNAIDS) report. They looked to national demographics to estimate HIV prevalence based on race. World Bank data provided information about the socioeconomic status of people with HIV.

ClinicalTrials.gov provided demographics on the participants of 10 Phase III trials of dolutegravir (including 7,714 participants), four of bictegravir (2,307 participants), eight of TAF (7,573) and two of doravirine (1,407 participants).

Breaking down the demographics of the global HIV population by race and sex, the study authors found that Black women have the highest prevalence, at 42%, and Black men have the next highest, at 30%. White men make up just 6% of all people with HIV worldwide.

More than 60% of people with HIV live in low- or low-middle-income nations; 68% of these individuals are Black and 23% are Asian.

In contrast, 76% of trial centers studying dolutegravir were in high-income nations, where 5% of the global HIV population lives, and 24% were in upper-middle-income nations. Fifty-one percent of the participants in all the trials analyzed were white men.

Even within upper-middle-income and high-income nations, the demographics of the dolutegravir

trials were not representative of the HIV population in those countries. Forty-nine percent of the participants in those trials were white men, compared with 31% of the HIV population in those nations.

Whites were overrepresented by 44% in the combined trials for the four ARVs in comparison with the global HIV population. Black women were underrepresented by 35%.

“Female safety data are insufficient despite drug approval in Europe and USA,” the study authors concluded. “HIV trials should be located in regions representing the global epidemic with no sex-based selection. Trials should aim for at least 50% female and 50% non-white recruitment to properly provide safety information.”

To read the study, click here.

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