In HPTN 083, a global, double-blind randomized controlled trial (RCT) conducted among 4566 cisgender men and transgender women (TGW) who have sex with men, long-acting injectable cabotegravir (CAB-LA) was superior to daily oral tenofovir disoproxil fumarate-emtricitabine (TDF/FTC) for HIV prevention. Participants were enrolled December 2016 - March 2020.

At the first planned interim review in May 2020, an independent data and safety monitoring board recommended the study be unblinded; in April 2021, the protocol was amended as an open-label extension (OLE) in which participants were offered the choice of open-label CAB-LA or to complete study participation with daily oral TDF/FTC.

United States (US) sites transitioned to OLE before other regions; thus this analysis is limited to US participants.

Methods

- Product choices were compared between the following demographic subgroups: age, gender, race, ethnicity, education, and original randomized regimen using chi-squared tests.
- Reported reason for choice of regimen is also described.

Results

In the post-unblinding OLE of a Phase 3 multinational RCT, nearly all US participants chose CAB-LA over oral TDF/FTC.

No specific subgroup drove this choice disparity.

General preference for either pills or injections largely dictated participants’ choice of regimen.

Data from the non-US participants in HPTN 083 will provide important insights into regional/cultural differences in product preference.

Limitations

This study is limited in that only half of US participants had product choice data available due in part to significant loss to follow-up. An additional limitation is that individuals preferring an oral PrEP regimen may not have chosen to enroll in HPTN 083.

Conclusions

Nearly all HPTN 083 participants from the US chose CAB-LA over oral TDF/FTC upon transition to the open-label extension phase of the study.

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