| **Study Author, year** | **Study design** | **Number of centers, Country** | **Study duration**  **Mean followup** | **Interventions** | **Inclusion criteria** | **Patient characteristics** | **Number screened, eligible, enrolled, analyzed**  **Withdrawals**  **Loss to followup** | **Quality rating** | **Funding source** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Chan, 2016124 | Cohort | 3  U.S. (Providence Rhode Island, Jackson Mississippi, St. Louis Missouri) | 20 months | Oral FTC and TDF | Patients at 1 of 3 clinics with behaviors associated with HIV acquisition | Total population  Mean age 32 years (SD, 10)  91% male; 8% female; >1% transgender  Race: 44% white; 41% black; 3% Asian; 13% other; 12% Hispanic/Latino  Risk behaviors: 89% MSM; 11% MSF; 7% FSM; 31% serodiscordant couple; 61% condomless anal sex with another man; 25% anal sex with HIV+ man  Substance use: Alcohol: 78%; PWID: 0%; methamphetamine: 2%; amyl nitrate ("popper"): 15% | Screened: NR  Eligible: 267  Enrolled: 267  Analyzed: 171  Withdrawals: 8  Loss to followup: 19 | Fair | Gilead Sciences, Inc. |
| Hosek, 201793  Project PrEPare, ATN 110 | Open-label PrEP demon-stration project and safety study | 12  U.S. | 48 weeks | TDF-FTC | HIV-uninfected YMSM, ages 18 to 22 years at time of signed informed consent | Mean age 20 years (SD, 1.3; median, 20 years)  100% male (at birth)  47% Black; 1% Asian; 21% white non-Hispanic; 11% white Hispanic; 21% other/mixed race  Risk factors: 81% condomless sex in the previous month; 58% condomless receptive anal intercourse with last partner; 22% any positive STI test | Screened: 2,186  Eligible: 400  Enrolled: 200  Analyzed: 142  Withdrawals: 58  Loss to followup: 34 | Fair | ATN: National Institutes of Health (Eunice Kennedy Shriver National Institute of Child Health and Human Development); National Institute on Drug Abuse; and National Institute of Mental Health. Study drug was donated by Gilead Sciences, Inc., along with supplemental funds for a portion of the dried blood spot testing. Various authors receive funding from Gilead. |
| Hosek 201792  Project PrEPare, ATN 113 | Cohort | 14  U.S. | 48 weeks | TDF-FTC | Ages 15 to 17 years, male at birth, HIV-uninfected, self-reported risk for HIV acquisition | Mean age 16.5 years (SD, 0.73)  3% Asian/Pacific Islander; 29% Black/African American; 14% white; 21% Hispanic; 33% other/mixed race/ethnicity  Risk behaviors: 17% ever been paid for sex; 3% exchanged sex for a place to stay; 87% engaged in high-risk sex acts with men; 60% unprotected receptive anal sex | Screened: 2,864  Eligible: 260  Enrolled: 78  Analyzed: 78  Withdrawals: 13  Loss to followup: 19 | Fair | ATN: National Institute of Child Health and Human Development; National Institute on Drug Abuse; National Institute of Mental Health. Study drugs were donated by Gilead Sciences along with funding for a portion of the dried blood spot testing and overall study costs. |
| *iPrEx-OLE*  Grant, 2014125 | Cohort | Multisite  U.S., Brazil, Peru, Ecuador, South Africa and Thailand | 72 weeks | TDF-FTC | HIV-uninfected former participants of 3 randomized PrEP trials | Participants who received PrEP (n=1,225; data missing for some participants)  Mean age NR; 18 to 24 years: 20%; 25 to 29 years: 26%; 30 to 39 years: 32%; ≥40 years: 22%  100% male (at birth); 11% transgender  Race NR  Risk behaviors: 100% reported anal intercourse with men; 34% condomless receptive anal intercourse; 20% ≥5 alcoholic drinks on days when drinking; 2% methamphetamine use; 9% cocaine use  STIs: 16% syphilis; 50% HSV2; 2% gonorrhea | Screened: NR  Eligible: 1,603  Enrolled: 1,345  Analyzed: 1,225  Withdrawals: 84  Loss to followup: 31 | Good | Gilead Sciences, Inc. U.S. National Institutes of Health  HIV  Prevention Trial Network |
| *iPrEx-OLE*  Glidden, 2016142 | Cohort | Same as Grant 2014 | Same as Grant 2014 | Same as Grant 2014 | Same as Grant 2014 | Same as Grant 2014 | Same as Grant 2014 | Same as Grant 2014 | Same as Grant 2014 |
| Landovitz 2017126 *PATH-PrEP* | Cohort | 2 centers U.S. | 48 weeks | TDF-FTC PrEP (n=278)  Study also included a postexposure prophylaxis group (PEP; n=23) | Self-identified MSM, MSMW, and transgender women age ≥18 years, HIV uninfected at study entry by rapid ELISPOT and viral load, with adequate screening laboratory parameters, and without symptoms suggestive of primary HIV infection | n=301 (PrEP: 278; PEP: 23; 19 of whom subsequently crossed over to PrEP group) Median age 34 years (range, 20–69) 100% male/transgender woman 50% white; 28% Hispanic; 11% black; 6% Asian/Pacific Islander; 5% other Risk behaviors: 77% any substance use in the past 30 days; 56% polysubstance use in the past 30 days; 12% methamphetamine use in the past 30 days; 3% injection drug use in the past 3 months; 61% binge drinking in past 12 months; 27% PEP use in the past 12 months; 84% unprotected anal intercourse in the past 30 days; 13% STI diagnosis | Screened: 328 Eligible: 307 Enrolled: 301 Analyzed: 283 Withdrawals: 23  Loss to followup: 52 | Fair | California HIV Research Program; Gliead Sciences; Center for HIV Identification, Prevention, and Treatment, University of California, Los Angeles Center for AIDS Research; National Center for Advancing Translational Sciences |
| Montgomery, 2016127 | Retrosp-ective cohort | 1 site U.S. | 6 months | Oral TDF-FTC | Patients receiving PrEP at an outpatient infectious disease clinic in Providence, RI, between February 2013 and June 2014 | Mean age 34 years (range, 18–58)  94% male  63% white non-Hispanic; 6% black non-Hispanic; 23% Hispanic/Latino; 9% other  Risk factors: 91% MSM; 2% MSMW; 6% WSM; 46% serodiscordant couple; 3% no insurance; 38% referred from STI clinic | Screened: NR  Eligible: NR  Enrolled: 50  Analyzed: 35  Withdrawals: NR  Loss to followup: NR | Fair | Gilead Grant. National Institute of Allergy and Infectious Diseases |
| *U.S. PrEP*  *Demon-stration Project*  Liu, 201681 and Cohen, 2015146 | Cohort | 3 sites U.S. | 16 months | TDF-FTC | Male at birth, age ≥18 years, MSM or transgender, fluent in English or Spanish, negative HIV antibody result at screening and enrollment, negative 4th-generation antibody-antigen test at screening | Mean age NR; 18 to 25 years: 20%; 26 to 35 years: 38%; 36 to 45 years: 24%; ≥45 years: 18%  99% male; 1% transgender women  48% white; 34% Latino; 7% black; 5% Asian; 6% other  Risk behaviors: 12% ≥5 drinks/day when drinking; 46% "popper" or other inhalant use; 20% cocaine or crack use; 15% methamphetamine use; 23% club drug use; 32% erectile dysfunction drug use; 44% marijuana use; 2% PWID in the last 3 months; 23% condomless insertive anal sex; 64% condomless receptive anal sex; 5% exchange sex in the last 3 months  STIs: 4% syphilis; 15% gonorrhea, any site; 14% chlamydia, any site; 17% rectal gonorrhea or chlamydia | Screened: 557  Eligible (at 48 weeks): 437  Enrolled (completed 5 visits): 383  Analyzed: 294 (attending followup visits)  Withdrawals: NA  Loss to followup: NA | Fair | National Institute of Allergy and Infectious Disesases; National Institute of Mental Health; National Institutes of Health;  Gilead (study drug) |
| van Epps, 2018128 | Retrosp-ective cohort | Database (Veterans Health Administration Corporate Data Warehouse) U.S. | 1 year | TDF-FTC PrEP (n=1,086) | Veterans with at least 1 TDF-FTC fill of more than 30 days in the observation period; no other fills for ART within 180 days of the date of first TDF-FTC fill; no ICD 9 or 10 diagnosis codes for HIV or HBV infection; no ICD 9 or 10 codes for needle-stick exposure within 60 days of the date of first TDF-FTC fill. | Mean age NR; 39% <35 years; 35% 35 to 49 years; 21% 50 to 64 years; 6% 65 to 79 years 4% female 22% black; 67% white; 6% other 21% substance use problem | Screened: NA Eligible: 1,086 Enrolled: 1,086 Analyzed: 1,086 Withdrawals: NA Loss to followup: NA | Fair | Veterans Affairs; Veterans Health Administration Office of Rural Health; Veterans Affairs Health Services Research & Development |

**Abbreviations:** ART=antiretroviral therapy; FSM=females who have sex with males; ELISPOT=Enzyme-Linked ImmunoSpot assay; FTC=emtricitabine; HSV2=herpes simplex virus 2; iPrEx-OLE=Pre-Exposure Prophylaxis Initiative–Open Label Extension study; MSF=males who have sex with females; MSM=men who have sex with men; MSMW=men who have sex with men and women; NA=not applicable; NR=not reported; PEP=post-exposure prophylaxis; PrEP=pre-exposure prophylaxis; PWID=persons who inject drugs; SD=standard deviation; STI=sexually transmitted infection; TDF=tenofovir disporoxil fumarate; U.S.=United States; WSM=women who have sex with men; YMSM=young men who have sex with men.