On Demand PrEP for Men at High Risk for HIV
IPERGAY
On Demand PrEP for Men at High Risk for HIV
IPERGAY: Study Design

**Study Design: IPERGAY Study**

- **Background**: Randomized, phase 3, double-blind, placebo-controlled trial conducted in France and Canada that investigated tenofovir DF-emtricitabine as on-demand preexposure prophylaxis for men who sex with men or transgender women

- **Inclusion Criteria** (400 enrolled)
  - 18 years of age or older and HIV seronegative
  - Men or TG women who have sex with men
  - Unprotected anal sex ≥2 partners in prior 6 months
  - Excluded if chronic HCV or HBsAg-positive
  - Excluded: CrCl <60 mL/min, glycosuria, proteinuria

- **Treatment Arms**:
  - Placebo: (on demand schedule*)
  - Tenofovir DF-emtricitabine: (on demand schedule*)

**On demand Schedule**: take loading dose of two pills of TDF-FTC or placebo with food 2 to 24 hours before sex, followed by a third pill 24 hours after the first pill and a fourth pill 24 hours later. With multiple consecutive episodes of sex, take one pill per day until until 48 hours after last sex.

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IPERGAY On Demand Dosing Schedule

HIV Exposure Event

Time

2 tabs 2-24 hours before sex (or 1 pill if most recent dose taken <7 days prior)

1 tab 24 and 48 hours after the last pre-sex dose

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IPERGAY Dosing Schedule with Ongoing HIV Exposures

Ongoing HIV Exposures

2 tabs 2-24 hours before sex (or 1 pill if most recent dose taken <7 days prior)

1 tab 24 and 48 hours after the last pre-sex dose

If sexual activity continues, then PrEP continues daily until 48 hours after last sex
*Otherwise, same process repeated with next exposure event

Due to high effectiveness of PrEP, participants unrandomized and all offered PrEP

Conclusions: “The use of tenofovir DF-emtricitabine before and after sexual activity provided protection against HIV-1 infection in men who have sex with men. The treatment was associated with increased rates of gastrointestinal and renal adverse events.”

The National HIV Curriculum is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

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