On Demand PrEP for Men at High Risk for HIV
IPERGAY
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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

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.”

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