On-Demand HIV PrEP for Men at High Risk for HIV

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

**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 have sex with men.

**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 2-pill loading dose of TDF-FTC or placebo with food 2-24 hours before sex, followed by a 3rd pill 24 hours after the 1st pill and a 4th pill 48 hours after the first 2 pills. With multiple consecutive episodes of sex, take 1 pill per day 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 On-Demand Dosing Schedule with Ongoing HIV Exposures

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<th>Time</th>
<th>Initial HIV Exposure</th>
<th>Ongoing HIV Exposures</th>
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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

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IPERGAY: Results

Number of HIV Infections

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

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HIV Acquisition Risk Reduction

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 supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $1,021,448 with 0% financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov. This project is led by the University of Washington’s Infectious Diseases Education and Assessment (IDEA) Program.