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On Demand PrEP With Oral TDF-FTC in MSM: Results of the ANRS Ipergay Trial

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Abstract Body:

Background : Daily PrEP with oral TDF-FTC can reduce the risk of HIV infection in high risk individuals but long term adherence to a daily regimen remains challenging and explains the discordant results reported across trials. We wished to assess the efficacy of “on demand” PrEP in high risk MSM.

Methods : High risk adult MSM who reported condomless anal sex and had a creatinine clearance > 60 mL/mn were enrolled in this prospective randomized double-blinded placebo-controlled study. Participants (pts) were asked to take two pills of TDF-FTC (300mg/200mg per pill) or placebo 2 to 24h before each sexual intercourse, then another pill 24h later and a fourth pill 48h after the first drug intake. All subjects received risk-reduction counseling, condoms, HBV and HAV vaccines when needed, were informed about post-exposure prophylaxis and were regularly tested for HIV and other sexually transmitted infections (STIs). The primary study objective was to demonstrate a reduction in HIV incidence with on demand PrEP. In November 2014, following the DSMB recommendation, the placebo arm was discontinued and on demand PrEP was offered to all participants.

Results : From February 2012 to November 2014, 414 pts were randomized and 400 without HIV-infection were enrolled. After a median follow-up of 8.8 months (IQR: 4.3 to 20.5), the incidence of HIV-infection was 6.75 per 100 pt-years in the placebo arm and 0.94 per 100 pt-years in the TDF-FTC arm indicating a relative reduction of 86% in the incidence of HIV with on demand PrEP (95% CI: 39.4-98.5%, P=0.002). Sixteen pts acquired HIV-infection after enrollment, 14 in the placebo arm and 2 in the TDF-FTC arm. Pts used a median of 14 pills/month (IQR: 8-20). Overall, 34% of pts acquired a new STIs. Safety was good with only one pt discontinuing TDF-FTC because of suspected drug-drug interaction. The rate of serious adverse events was low (9%) and similar across the study arms. Drug-related gastrointestinal adverse events (nausea, diarrhea, abdominal pain) were reported more frequently with TDF-FTC than with placebo (13% vs 6%, p=0.02). Only 2 pts (1%) in the TDF-FTC arm had transient decreases in creatinine clearance

Conclusion : On demand PrEP with oral TDF-FTC is highly effective to reduce the incidence of HIV-infection in high risk MSM and has a good safety profile.