

## Ipergay trial: PrEP still protected people who had less sex and used it less often

A substudy of the French Ipergay trial of 'on-demand' PrEP has found that PrEP was just as effective for participants who had sex less often than average, and so took PrEP less often, as long as they did take it when it was needed.

The analysis was presented at the [IAS 2017](#) conference yesterday by trial statistician Guillemette Antoni.

The substudy was done because although Ipergay was a trial to see if PrEP worked only when taken as needed, some commenters, and indeed the trial researchers themselves, noted that a lot of Ipergay participants were having sex and taking PrEP so often that they were effectively taking it almost daily.

The Ipergay regimen involved taking a double dose of PrEP in the 24 hours before sex risking HIV infection was anticipated, and then taking a pill on each of the following two days; the regimen therefore covered three days, so anyone who was regularly having sex that risked HIV more than twice a week was almost taking full-time PrEP anyway.

This posed the possibility that Ipergay was not really measuring the effectiveness of PrEP that was only used when needed.

The substudy therefore looked at PrEP use and HIV infections, during the placebo-controlled phase of the study, in people who took less than the median number of pills as measured by clinic returns (15 or less a month).

People might, of course, be using fewer than the average number of pills because their PrEP use was erratic or they were not having sex at all. Ipergay participants were interviewed at every two-monthly clinic visit and were asked if they had used PrEP during risky sex a) systematically, b) often, c) only now and then or d) not at all. The sub-analysis then only looked at the men who said they were using PrEP systematically, but actually used fewer pills than average; this being the closest approximation to those men who were using PrEP according to the trial protocol, despite only occasional risky sex.

Two-thirds of the trial participants fell into this category during at least one two-month period during their participation (269 out of 400). But because their sex lives, and therefore PrEP use, changed through the study, they did not fall into this category at every visit. The actual number of person-years spent in this category was 134 out of a

total of 431.3 person-years in the study, representing 31% of time spent in the study.

The median number of occasions of sex in this subgroup was five times a month or only just over once a week, but 25% were having sex twice a month or less. The number of pills taken per month averaged 9.5, but 25% were taking six a month or fewer.

The researchers then looked at HIV infections and found that six of the 16 infections during the study happened in this group of people. However all six of them were taking placebo and none were randomised to *Truvada*.

This means that in this subgroup of patients who had less risky sex than average but used PrEP consistently, it protected them completely. Although there were fewer patient-years in this group than in the whole study, the 95% confidence interval for this result was similar (39% - 100%) and the probability of it being a chance result was low ( $p = 0.013$ ). Notably, annual HIV incidence in the men in this group on placebo (9.3% per person-year) was statistically equivalent to that seen in the study in general (6.6%), though numerically higher.

PrEP, of course only worked, even in people who only had sex occasionally, if they took it correctly when they did have sex. There were two infections in men randomised to *Truvada* in the trial, but both had stopped taking it by the time they were infected.

Ipergay principal investigator Jean-Michel Molina commented: "Although the number of person-hours in this substudy was small, we hope it will add to the evidence that on-demand PrEP is effective.

"Now than more than 3000 people are taking PrEP through the public health system in France, with over half of them taking it on demand, we expect to see more evidence of its effectiveness."

Antoni G et al. *On-demand PrEP with TDF/FTC remains highly effective among MSM with infrequent sexual intercourse: a sub-study of the ANRS IPERGAY trial*. IAS2017 conference, Paris. Abstract number TUAC0102. 2017. [See slides, session video and rapporteur summary here.](#)