

Press release

A SIGNIFICANT BREAKTHROUGH IN THE FIGHT AGAINST HIV/AIDS

A drug taken at the time of sexual intercourse effectively reduces the risk of infection

The ANRS IPERGAY trial demonstrates the effectiveness of a preventive treatment (antiretroviral treatment) against HIV/AIDS when taken at the time of sexual intercourse. All trial participants will now benefit from this prophylaxis.

More than 6000 people discover their HIV status in France each year. Sexual transmission accounts for 99% of these infections. It is therefore an urgent priority to develop new prevention approaches especially for the most at-risk groups to be infected. Men who have sex with men (MSM) represent 42% of these new cases, and are therefore a key population to target.

Over the last couple of years, several research teams around the world have tried an original approach for prevention seeking to reduce the risk of HIV infection using antiretroviral drugs. The concept of pre-exposure prophylaxis, or PrEP, using daily antiretroviral drugs has so far shown mixed results in the different populations studied.

The IPREX trial among MSM showed that the HIV infection rate was reduced by 42% among those using daily PrEP with two antiretroviral drugs (tenofovir / emtricitabine: Truvada®) as compared to those receiving a placebo. More recently, the PROUD study conducted in MSM in the UK randomized participants to either immediate or deferred PrEP (after one year) using daily Truvada®. The PROUD data safety monitoring board (DSMB) recommended, on October 16 2014, to give daily PrEP to all trial participants in the deferred arm in light of interim results showing that PrEP was "highly protective against HIV." No detailed data were shown in this announcement.

The ANRS IPERGAY trial:

The ANRS (France REcherche Nord&Sud Sida-hiv Hépatites) IPERGAY trial differs from the other two trials by using "on demand" prophylaxis only at the time sexual intercourse. Coordinated by Professor Jean-Michel Molina (University Paris-Diderot Paris 7, and Saint-Louis hospital, Paris), the trial began in February 2012 in MSM at high risk of HIV-infection. As part of a global and combined prevention framework, a package of measures are offered to the participants (personalized and frequent counseling, repeated HIV testing, screening and treatment for other sexually transmitted infections, hepatitis B vaccination, condoms and gel distribution). Participants were randomized in two groups: one group received on demand Truvada®, the other group its placebo. Tablets, provided by Gilead laboratories, are taken at the time of sexual intercourse. This double-blind trial (neither the participants nor the doctors know the treatment received) is being conducted in France with more than 400 volunteers (Paris: Saint-Louis hospital and Tenon hospital. Lyon: Croix-Rousse hospital. Nantes: Hôtel-Dieu university hospital. Nice: Archet hospital. Tourcoing: Gustave Dron hospital) and Canada (Montreal university hospital). The trial particularity also relies on the

active participation of the AIDES community group and close collaboration with a community advisory board comprising several gay community groups.

Following the decision taken by the PROUD team to give daily Truvada® to all participants, the ANRS urgently contacted the IPERGAY trial data safety monitoring board (DSMB) .

The recommendation given to the ANRS

The ANRS IPERGAY' DSMB exchanged with its counterpart of the PROUD trial. The DSMB then examined the "unblinded" data from the ANRS IPERGAY trial, ie examined the incidence rate of HIV infection (number of new cases) in the two groups of participants (the group receiving "on demand" Truvada® and the group receiving its placebo).

The DSMB found a significant difference in incidence between the two groups with a very significant reduction in the risk of HIV infection in the on demand PrEP group, much higher than the one observed in the IPREX trial. The DSMB therefore recommended that all trial participants will benefit from "on demand" Truvada®.

The ANRS decision

This recommendation was immediately endorsed by the ANRS and by the trial Scientific Committee. The ANRS decided:

- Truvada® will be made available to all participants of the ANRS IPERGAY trial. Participants will be contacted to make an appointment as soon as possible at their trial site.
- Regulatory and ethical procedures related to this change will be implemented and trial partners and health officials informed.

The full results of the ANRS IPERGAY trial should be available early 2015. The trial will continue for at least a year. It is indeed important to ensure the continued long term benefit of "on demand" PrEP and also assess its long-term safety.

According to Professor Jean-Michel Molina: *"The biomedical concept of on demand PrEP at the time of sexual exposure, in a broader prevention framework, is validated. We owe it to all trial volunteers without whom we could never have achieved these results".* He adds : *" We must not forget that condoms remain the cornerstone of HIV prevention. Combining all prevention tools that have proved to be effective will certainly allow us to better control the HIV/AIDS epidemics "*.

According to Professor Jean-François Delfraissy, Director of ANRS, *"This is a major breakthrough in the fight against HIV. The results of the ANRS IPERGAY trial should change national and international recommendations towards HIV prevention".*

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