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Press release

Risk of HIV infection reduced by 86% in ANRS Ipergay trial

Preventive antiretroviral treatment taken at the time of sexual intercourses reduces the risk of HIV infection by 86% in men who have sex with men, who are at high risk of infection because of their sexual practices. The results of the first phase of the ANRS Ipergay trial will be reported in an oral communication on 24 February 2015 at the 22nd Conference on Retroviruses and Opportunistic Infections (CROI 2015) in Seattle.

Iprex, the reference study of pre-exposure prophylaxis (PrEp) in men who have sex with men (MSM), has shown that it is possible to reduce the risk of HIV infection by approximately 44% by a daily dose of an antiretroviral, Truvada® (a combination of tenofovir and emtricitabine). The ANRS Ipergay trial has now provided the first scientific demonstration that "on demand" preventive treatment taken by MSM at the time of unprotected sex reduces the risk of HIV infection by 86%. This study was conducted within the framework of a sexual health program including community-based support.

The French Research Agency ANRS is the sponsor and main source of funding of the ANRS Ipergay trial, which since 2012 has been conducted in 414 MSM in a randomized, double-blind design (one half of the subjects take Truvada® at the time of sexual intercourses, the others take a placebo). A package of preventive measures was offered to all participants: personalized counseling, distribution of condoms and gel, repeated HIV testing, screening for and treatment of other sexually transmitted diseases, vaccination against hepatitis B and A, readily available post-exposure treatment, and so forth. After an average follow-up of close to 13 months, 16 participants were infected by HIV: 14 in the placebo arm and 2 in the Truvada® arm. The relative risk of infection was therefore reduced by 86% (95% confidence interval: 40-99%). The 2 infected participants in the Truvada® arm had discontinued PrEp several weeks before the occurrence of infection. There was, moreover, a very high incidence of infection (6.6%) in the placebo arm among participants who did not use condoms routinely.
Truvada® was generally well tolerated: it was not associated with more severe side effects than placebo, but was associated with a higher risk of mild nausea and abdominal pain (13% with Truvada® versus 6% with placebo).

Professor Jean-François Delfraissy, Director of ANRS, points out that "*While we have today provided a real innovation in the prevention of HIV infection, we have also been innovative in the way we conducted the research, by setting up a highly original partnership with nonprofit organizations. We drew up the research protocol with AIDES, which shared the follow-up work and played a major role in recruiting and supporting participants, and a community advisory board, made sure throughout the study that the research was conducted in the interests of the participants.*"

The ANRS Ipergay results were recorded in one of the populations most affected by HIV infection today in France and in most developed countries. Of approximately 6400 new diagnoses of HIV infection every year in France, 43% are in MSM. Bruno Spire, President of AIDES and trial co-

investigator, notes that "*The support provided by the AIDES teams certainly improved good adherence, which is essential for the efficacy of the preventive treatment*."

Study coordinator Professor Jean-Michel Molina (Université Paris 7 – Hôpital Saint-Louis, AP-HP, Paris) observed that "*these very good results were obtained in MSM at high risk of HIV infection who did not routinely use condoms*." He pointed out that during the study 34% of the participants contracted another sexually transmitted disease, like gonorrhea, syphilis, hepatitis C or Chlamydia infection. He added: "*It is important not to abandon the prevention policies that have proven effective so far: routine use of condoms, regular screening for HIV infection and other sexually transmitted diseases, and their treatment*."

All study participants have been receiving Truvada® since October 2014. Follow-up will continue until March 2016. This second phase of the study will be used to confirm the efficacy and safety of PrEp with Truvada® over a longer period and to study its impact on sexual behavior. In this regard, ANRS and AIDES applaud the long-term commitment of the Ipergay volunteers.

Professor Delfraissy points out that "*ANRS Ipergay is undeniably a step towards a better overall prevention strategy combining several tools to limit the risk of infection as a function of the degree of exposure*." Whereas most such tools are available today, Truvada® is not currently authorized in France for prevention of HIV infection. In this regard, Bruno Spire notes that "*AIDES has asked the French Agency for the Safety of Health Products to approve a temporary recommendation for use of Truvada®, broadening the conditions for access to include people vulnerable to HIV infection. We hope that the present results will accelerate this process*."

ANRS Ipergay trial:

Launched in February 2012, ANRS Ipergay included 414 seronegative men who have sex with men (MSM) and who are at high risk of HIV infection because of their sexual practices. These trial participants are located in France (Paris: Hôpital Saint-Louis, AP-HP, and Hôpital Tenon, AP-HP. Lyon: Hôpital de la Croix-Rousse. Nantes: CHU Hôtel-Dieu. Nice: Hôpital de l'Archet. Tourcoing: Hôpital Gustave Dron) and Canada (CHU de Montréal). Professor Jean-Michel Molina (Université Paris 7 – Hôpital Saint-Louis, AP-HP, Paris) is the ANRS Ipergay coordinator.

ANRS Ipergay is a randomized, double-blind trial (neither the participants nor the physicians know which treatment is received) begun in 2012. The participants were randomly assigned to one of two treatment arms: Truvada® or placebo. Gilead supplied the treatments, which were started before sexual relations and stopped afterwards. Each participant benefitted from a package of preventive measures. All participants have been included in the Truvada® arm since October 2014.

The nonprofit organization AIDES helped write the protocol and participated in study follow-up, within the framework of community-based research. AIDES also took part in the recruitment of volunteers and provided them with prevention support. A LGBT committee of several nonprofit organizations, made sure that the interests of the participants were respected.

SC10-US019 of Inserm (Villejuif), headed by Professor Laurence Meyer, coordinated the study. The study is supported by , CIHR Canadian HIV Trials Network, the Bill & Melinda Gates Foundation and the Pierre Bergé endowment fund.

Abstract

On demand PrEP with oral TDF-FTC in MSM: Results of the ANRS Ipergay trial

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