CTN 268 Anrs
IPERGAY Trial

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About the study

This study will test to see if the pill TDF/FTC (Truvada®) can offer protection against HIV infection if taken on an intermittent or 'on demand' basis as pre-exposure prophylaxis (PrEP). The medication has been shown to have some effectiveness as a tool for preventing HIV when taken on a daily basis, but the effectiveness of daily PrEP is very much dependent on adherence to treatment. When compared to daily use, on-demand PrEP could have significant benefits such as easier adherence that would make the treatment more effective, as well as lower costs. However, more needs to be learned. Trial researchers are seeking to recruit adult men who have sex with men, who are HIV-negative but who are exposed by their sexual relations to the risk of HIV infection. The researchers have developed a placebo controlled randomized study to evaluate the effectiveness and safety of "on demand" prophylactic treatment in men having sex with men at a high risk of HIV. The placebo is a pill containing no medication. The study will be double-blind so neither participants nor researchers will know who is receiving the study drug or a placebo. Community representatives are directly involved in the implementation of the study and will be consulted at all stages of the project.

About the condition

Risk of HIV infection continues to be a serious health concern. In Quebec, the rate of HIV infection rose between 1997 and 2002. Study researchers have noted that in 2009 men who have sex with men accounted for the highest population with new HIV diagnoses in Quebec. Current prevention strategies such as the use of condoms have been shown to be effective but also limited in a context of at-risk sexual behaviour. Study researchers seek to identify an additional approach to the prevention of HIV infection that can work with current measures such as the use of condoms.

Eligibility criteria

Inclusion

- be 18 years old and up
- be male or transgender, having sex with men
- not HIV-1 or HIV-2 positive
- have an elevated risk for exposure to HIV, i.e., have had anal sexual relations with at least 2 different partners in the past 6 months without the systematic use of a condom
- have satisfactory kidney function
- have satisfactory liver function (measured with an ALT less than 2.5 times the value above normal)
- have lab tests with neutrophil granulocytes greater than or equal to 1 000/mm3, haemoglobin of greater than or equal to 10 g/dL and platelets of greater than or equal to 150 000/mm3 (blood components)
- not hepatitis B or hepatitis C positive

Exclusion

- history of chronic kidney disease, osteoporosis, osteopaenia (decrease in bone density)
- history of pathological bone fracture not related to trauma
- treatment with Interferon, Interleukin, corticosteroids or antiretrovirals
- treatment which could prevent elimination of the antiretrovirals via the kidneys
- treatment during the investigation (participation in another trial)
- administration (during or expected) of a treatment that may be toxic to the kidneys (long-term anti-inflammatory)
- taking intravenous drugs
- a gastro-intestinal disease (or chronic nausea or vomiting) disrupting the absorption of treatments
- serious disease which could require a treatment that could disrupt the compliance of the treatment

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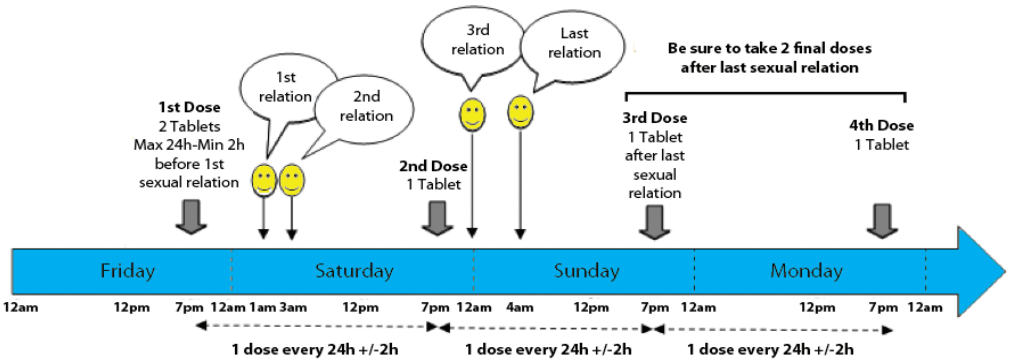
About the approach

Participants will be randomly selected to either join the study drug arm or the placebo arm of the study. In addition to the placebo controlled study drug, all participants will be asked to schedule regular visits to a clinic and be offered a complete prevention package to reduce risk (individual support, counselling, screening for HIV and sexually transmitted infections, condoms, lube, and vaccinations for hepatitis A and B).

The dosage of Truvada® or Truvada® placebo is the following:

- 2 tablets within 24 hours before first sexual relations, with a meal or a snack if possible (at the earliest 24 hours and no later than 2 hours before first sexual relations)
- then 1 tablet every 24 hours (starting when the first two tablets are taken) with a meal or a snack if possible, during the period of sexual activity including after the last sexual relation,
- finally, a last dose of 1 tablet of Truvada® or placebo, approximately 24 hours after the previous tablet, with a meal or a snack if possible.



Participants will be asked to follow a trial calendar that provides a schedule of visits with researchers, exams performed and questionnaires to be completed at the time of each visit. Participants will also be asked to participate in several sub-studies connected to the IPERGAY trial.

This study is sponsored by the French National Agency for AIDS Research (L'Anrs) and its initial phase will be conducted in France and Quebec. It will be conducted in two stages. This first stage will enrol 100 participants in Montreal and 200 in France. During this stage, researchers will evaluate the possibility for broader recruitment in France and Canada and will review the tools put into place as part of the trial. If the first stage is successful, the trial will be expanded to enroll 1600 additional participants in France, Canada and other countries.

IPERGAY PARTNERS

- Centre hospitalier de l'Université de Montréal (CHUM)
- McGill AIDS Centre
- Clinique médicale l'Actuel
- Clinique médicale Quartier latin
- Coalition des organismes communautaires québécois de lutte contre le sida (COCQ-SIDA)
- RÉZO
- SPOT
- Université du Québec à Montréal (UQAM)

PARTICIPATING SITES

- Centre hospitalier de l'Université de Montréal (CHUM)

FUNDING PARTNERS

- Agence nationale de recherches sur le sida et les hépatites virales
- CIHR Canadian HIV Trials Network