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Preventing HIV

A major study published in the *New England Journal of Medicine* demonstrates the effectiveness of a new HIV prevention tool, Pre-Exposure Prophylaxis (PrEP).

IN a finding with the potential to fundamentally change strategies to slow the global HIV epidemic, a new study called iPrEx shows that individuals at high risk for HIV infection who took a single daily tablet containing two widely used HIV medications, emtricitabine and tenofovir (FTC/TDF), experienced an average of 43.8% fewer HIV infections than those who received a placebo pill.

The study, reported a few days ago in the *New England Journal of Medicine*, is the first evidence that this new HIV prevention method, called pre-exposure prophylaxis or PrEP, reduces HIV infection risk in people.

"We were excited to be a part of this major HIV prevention trial," said Peter Anderson, PharmD, associate professor at the University of Colorado School of Pharmacy. "We're pleased that the drug level information that we contributed was useful in the interpretation of the overall study results. We look forward to continuing our work with the study team, and through our own studies here, to better understand how drug levels contribute to safety and efficacy for HIV prevention."

A total of 2,499 individuals at high risk of HIV infection participated in the six-country iPrEx study. All study participants received a comprehensive package of prevention services designed to reduce their risk of HIV infection throughout the trial, including HIV testing, intensive safer sex counseling, condoms, and treatment and care for sexually transmitted infections. Half of study participants also received the PrEP pill, while the other half received a placebo.

In all, 64 HIV infections were recorded among the 1,248 study participants who received a placebo pill, while 36 HIV infections were recorded among the 1,251 participants who received the study drug. The average reduction in HIV infection risk of 43.8% includes all study participants – even those who did not take the daily pill consistently.

The iPrEx study found that PrEP was more protective among those who reported taking the pill more regularly. Among participants who used the tablet on 50% or more of days, as measured by pill counts, bottle counts, and self-reports, risk of HIV infection fell by 50.2%.

Among those who used the pill on 90% or more of days, as determined by the same measures, the PrEP pill reduced infection risk by 72.8%.

While pill-taking measures that rely on self-reports are not objective, testing to measure levels of the PrEP drug in the blood of study participants – a more reliable measure of pilltaking – also indicated that those participants who were protected against HIV infection were likely taking the study drug more regularly.

Among a subset of study participants who received the active drug, detectable levels of the PrEP drug combination were found in the blood of 51% (22 of 43) of a group that remained HIV-negative, but in only 9% (three of 34) of participants who became HIV infected.

Low or absent drug levels underlay all of the infections that occurred among those who received active PrEP, while those who used the drug more regularly had higher levels of protection against HIV infection. Drug levels were analysed in the Colorado Antiviral Pharmacology Laboratory at the University of Colorado School of Pharmacy.

"The iPrEx study proves that PrEP provides important additional protection against HIV when offered with other prevention methods such as HIV testing, counseling, condom use, and management of sexually transmitted infections," said iPrEx protocol chair Dr Robert Grant, of the Gladstone Institutes and the University of California at San Francisco. "As with other prevention methods, the greatest protection comes with consistent use. I hope this finding inspires a renewed commitment from communities, industry and government to stop the spread of HIV."

"iPrEx is a significant advance in HIV prevention," said Dr Javier R. Lama, the co-chair of the study protocol who is based in Lima, Peru. "Thanks to the extraordinary efforts of our study participants, their families and communities, iPrEx shows that a preventive drug can significantly reduce HIV infection risk. Further research is now needed to opti-

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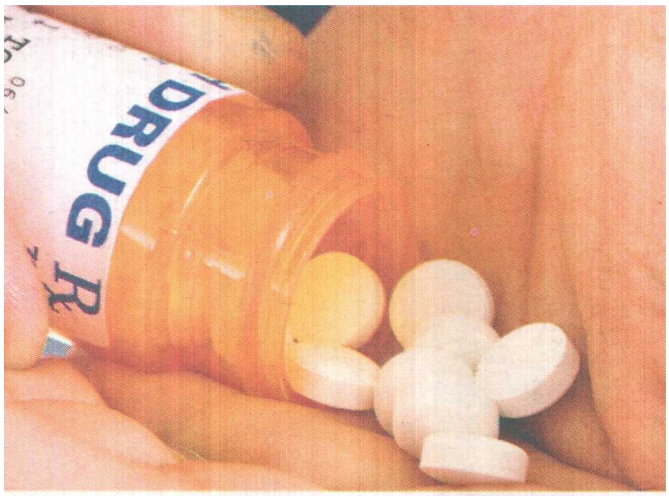
mise the efficacy of oral PrEP based on iPrEx results."

About the iPrEx study

The iPrEx study (Iniciativa Profilaxis Preexposicion or Prexposure Prophylaxis Initiative) is a double-blind, placebo controlled Phase III clinical trial that began in 2007 following three years of community consultation. iPrEx is the first human efficacy study of PrEP to report data.

In all, 2,499 men and transgender women who have sex with men at high risk for HIV infection participated in the iPrEx study at 11 sites in Brazil, Ecuador, Peru, South Africa, Thailand and the United States.

In July, 2010, a study known as CAPRISA 004 found evidence that a topical gel containing 1% tenofovir helped reduce HIV negative women's risk of HIV infection via vaginal sex. The topical gel is another form of HIV prevention using antiretroviral drugs currently being explored, in addition to oral PrEP. – HealthNewsDigest.com



Use of certain HIV medications reduces risk of HIV infection in uninfected people. – AFPRelaxnews