ARCA
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Preliminary Results Released in Vienna for US Safety Study of Tenofovir for Prevention of HIV in Men Who Have Sex with Men

121 Atlanta Men Participated Through AIDS Research Consortium of Atlanta

Vienna, Austria. Preliminary results from the Phase II safety study of tenofovir taken daily for HIV prevention among gay and bisexual men who have sex with men (MSM) were presented today at the XVIII International AIDS Conference in Vienna, Austria. The study, funded by the US Centers for Disease Control and Prevention (CDC), was conducted by the AIDS Research Consortium of Atlanta (ARCA), the San Francisco Department of Public Health, and Fenway Community Health in Boston. The study findings were presented today by Dr. Lisa Grohskopf of the CDC. ARCA's Principal Investigator Dr. Melanie Thompson was a senior author on the study. Preliminary analyses from the first study to examine the clinical and behavioral safety suggest no significant safety concerns.

The approach of taking a daily antiretroviral drug to try to prevent HIV infection is known as pre-exposure prophylaxis, or PrEP, and studies around the world are currently underway to determine if it is effective at reducing HIV infection among individuals at high risk, including MSM. While the results of those studies will be needed to determine if PrEP can prevent HIV, this safety study lends additional assurance that the strategy may be safe among MSM, should it prove effective.

Methods

The trial examined whether a 300 mg tablet of tenofovir disoproxil fumarate taken daily was safe among 400 HIV-negative men who have sex with men. The study would not have been possible without the commitment and dedication of the trial participants.

Study participants were randomly assigned to one of four study arms: 1) daily tenofovir pill beginning immediately at enrollment; 2) daily tenofovir pill beginning nine months after enrollment; 3) daily placebo (dummy) pill beginning immediately; or 4) daily placebo pill beginning nine months after enrollment. This study design allows analysis of both the medical safety of taking tenofovir daily (compared to the placebo pill), and the effect of taking a daily pill (compared to not taking a pill) on behavioral risk practices. Clinical safety was assessed through regular study visits and laboratory testing among all participants.. All participants in the study received regular HIV education, extensive risk-reduction counseling, free condoms, free HIV testing and STD testing and treatment throughout the trial.

Study Results

The study enrolled 400 men at the three sites. The median age was 39 years. Overall race was: 73% white, 15% African American, 4% Asian-Pacific Islander with 9% identifying as Hispanic.

ARCA enrolled 121 patients, of whom 32% were non-white (27% African-American, 1% Asian-Pacific Islander, 4% other races) and 12% were Hispanic. ARCA enrolled the highest proportion of non-white participants, especially African-Americans, of any study site.

A total of 373 men received tenofovir or placebo during the study. The preliminary analysis found no significant safety concerns associated with tenofovir. There was no significant difference between the number of adverse events seen in the groups that took tenofovir and the groups that took placebo. Some symptoms, like stomach/intestinal complaints and depression were common in all groups with no difference between men taking tenofovir or those taking placebo. Problems with kidney function were uncommon in all groups, and not statistically different. Serious adverse events (SAE's) occurring during the study were equally balanced between the tenofovir group and the placebo group and none in the tenofovir group were judged to be related to taking tenofovir.

In addition to clinical safety, another key objective of this study was to assess the potential impact of a daily preventative drug regimen on HIV risk behaviors. One of the greatest risks, should PrEP prove to be partially effective at reducing HIV transmission, is that those using PrEP might increase their risk behaviors—a phenomenon called "behavioral disinhibition," or "risk compensation." While analysis of behavioral safety data are not yet complete, preliminary analyses suggest there was no overall increased unprotected anal sex in men taking a study pill compared to those not taking a study pill during their first nine months of study participation.

Only three HIV infections occurred among trial participants while taking study pills. All three occurred in the placebo arm, but that could be entirely by chance. Four additional HIV infections occurred in the trial, but one occurred prior to the first study visit and the other three were on the delayed arm and had not yet received drug. More analyses, including analysis of study drug adherence, are planned and will be presented in the future. No conclusions about the potential efficacy of PrEP in preventing HIV infection can be drawn from this study, as it was not designed to assess effectiveness.

Conclusions

This trial is one of many studies evaluating the safety and acceptability of PrEP among populations at high risk for HIV around the world. PrEP is one of the most promising new prevention approaches being explored, and if effective, could help address an urgent need for additional tools – used in addition to condoms and traditional risk-reduction methods - to help slow the HIV epidemic in the U.S. and around the world. The findings of this study, in conjunction with other PrEP trials underway, can guide planning for future research and guidance for the counseling, prevention services, and safety monitoring that would need to be implemented in conjunction with PrEP, if it proves effective.

"We are extremely pleased with the outcome of the study," said Melanie Thompson, MD, ARCA's Principal Investigator and an author on today's presentation. "We need to explore many different avenues to prevent HIV infection, an epidemic that disproportionately affects African-Americans and gay and bisexual men of all races in the United States. If other studies show that PrEP is effective, millions of infections could be prevented globally." It is estimated that 56,000 new HIV infections occur in the US every year, and over 2.7 million are infected around the world on an annual basis.

More information about other PrEP studies is available at www.prepwatch.org. For more complete information on implementation planning in the U.S., see separate CDC fact sheet "Pre-Exposure Prophylaxis (PrEP) for HIV Prevention: Planning for Potential Implementation in the U.S." (http://www.cdc.gov/hiv/prep/resources/factsheets/implementation.htm). For more information on CDC's PrEP trials, see CDC fact sheet "CDC Trials of Pre-Exposure Prophylaxis for HIV Prevention" (http://www.cdc.gov/hiv/prep/resources/factsheets/index.htm)

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About the AIDS Research Consortium of Atlanta

ARCA is a registered 501(c)(3) not-for-profit clinical research, testing, outreach and educational organization founded in 1988. ARCA works through a network of more than 50 physicians and 5 public health clinics to conduct clinical drug and vaccine trials and prevention research studies. ARCA also provides patient and care-provider educational programs, free STD testing for men, and free, anonymous HIV testing when funds are available. More than 5000 Atlantans have learned their HIV status through ARCA's HIV testing program.

ARCA has become a leading HIV/AIDS research facility over the past two decades by enrolling more than 2,000 metro Atlanta residents in more than 300 clinical drug trials that provide the latest investigational HIV/AIDS medications at no cost to them. ARCA has contributed key scientific information leading to the FDA approval of more than 27 individual and combination drugs now available for people with HIV/AIDS worldwide. In all, more than 20,000 Atlantans have participated in ARCA studies and services. For more information, visit www.arcatlanta.org.