

AIDS prevention pill study halted; no benefit seen

April 18 2011, By MARILYNN MARCHIONE , AP Medical Writer

Researchers are stopping a study that tests a daily pill to prevent infection with the AIDS virus in thousands of African women because partial results show no signs that the drug is doing any good.

Women taking Truvada (true-VAH'-duh), made by Gilead Sciences Inc., are just as likely to get HIV as other women who have been given dummy pills, an interim analysis of the study found. Even if the study were to continue, it would not be able to determine whether the pills help prevent infection, since the results are even this far along, researchers said.

The finding is disappointing because another study last fall concluded that Truvada did help prevent infections in gay and [bisexual men](#) when given with [condoms](#), counseling and other prevention services. Many AIDS experts view that as a breakthrough that might help slow the epidemic.

Family Health International, a nonprofit involved in AIDS research, announced the new results on Monday. The group launched the study two years ago and had enrolled about half of the 3,900 women intended in Kenya, Tanzania and South Africa. As of last week, 56 new HIV infections had occurred, half in each group.

No safety problems were seen with Truvada. However, women taking it were more likely to become pregnant than those on dummy pills.

"That's both a surprising finding and one that we can't readily explain" by what is known so far about Truvada's effects on women using [hormonal contraceptives](#), said Dr. Timothy Mastro of Family Health International. The study was sponsored by the U.S. Agency for International Development and the Bill & Melinda Gates Foundation. Gilead provided the drugs for the study.

Truvada already is sold for treating HIV. It's a combination of two drugs, tenofovir and emtricitabine, or FTC, made by California-based Gilead Sciences Inc.

Using it or its components for prevention is still "very promising," Mastro said, although benefits and risks may vary by gender and by the way the virus is spread - sex between men and women or riskier anal sex among men, for example.

Last year, a study in South Africa found that a vaginal gel spiked with tenofovir cut in half a woman's chances of getting HIV from an infected partner. Protection was greater for those who used it most faithfully.

A similar effect was seen in the study of Truvada in gay men. The drug lowered the chances of infection by 44 percent, and by 73 percent or more among men who took their pills most faithfully. The U.S. Centers for Disease Control and Prevention recently gave advice to doctors on prescribing Truvada along with other prevention services for gay men, based on those encouraging results.

In the new study, "it's difficult to understand why they did not see protection," but blood samples may tell more about whether it's related to how faithfully women took the pills, said Dr. Robert M. Grant of the Gladstone Institutes, a private foundation affiliated with the University of California, San Francisco.

He led the study of Truvada in [gay men](#) and said, "we are very confident that this approach is useful" for them.

The new study's result "must be seen as what it is - the closure of a single trial in a field that has generated exciting results in the recent past," said Mitchell Warren, head of the AIDS Vaccine Advocacy Coalition, a nonprofit group that works on [HIV](#) prevention research.

Two other large studies testing [AIDS](#) drugs for prevention are under way in Africa, in heterosexual [women](#) and in couples where one has the [virus](#) and the other does not. Results are expected within two years. The studies have mostly been in countries with high rates of new infections because that makes it easier to see whether a prevention measure is having an impact.

Truvada costs \$5,000 to \$14,000 a year in the United States, but as little as \$140 a year in some poor countries where it's available in generic form.

More information:

CDC: www.cdc.gov/hiv/prep/resources/qa/index.htm

AIDS information: www.aidsinfo.nih.gov

and www3.niaid.nih.gov/topics/HIVAIDS/

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