Daily Pill Greatly Lowers AIDS Risk, Study Finds


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In a development that could change the battle against AIDS, researchers have found that taking a daily antiretroviral pill greatly lowers the chances of getting infected with the fatal virus.

In the study, published Tuesday by the New England Journal of Medicine, researchers found that the hundreds of gay men randomly assigned to take the drugs were 44 percent less likely to get infected than the equal number assigned to take a placebo.

But when only the men whose blood tests showed they had taken their pill faithfully every day were considered, the pill was more than 90 percent effective, said Dr. Anthony S. Fauci, head of the division of the National Institutes of Health, which paid for the study along with the Bill and Melinda Gates Foundation.

“That’s huge,” Dr. Fauci said. “That says it all for me.”

The large study, nicknamed iPrEx, included nearly 2,500 men in six countries and was coordinated by the Gladstone Institutes of the University of California, San Francisco.

The results are the best news in the AIDS field in years, even better than this summer’s revelation that a vaginal microbicide protected 39 percent of all the women testing it and 54 percent of those who used it faithfully.

Also, the antiretroviral pill — Truvada, a combination of two drugs, tenofovir and emtricitabine — is available by prescription in many countries right now, while the microbicide gel is made only in small amounts for clinical trials.

The protection, known as “pre-exposure prophylaxis” or “PreP,” is also the first new form available to men, especially men who cannot use condoms because they sell sex, are in danger of prison rape, are under pressure from partners or lose their inhibitions when drunk or high.

It is a form of protection “that does not involve getting permission from the other partner, and that’s important,” said Phill Wilson, president of the Black AIDS Institute, which focuses on the epidemic among blacks.

Michel Sidibé, the head of UNAIDS, the United Nations AIDS-fighting agency, called it “a breakthrough that will accelerate the prevention revolution.”
Because Truvada is available now, some clinicians already prescribe it for prophylaxis, Dr. Fauci said, but whether doing so becomes official policy will depend on discussions by the Centers for Disease Control and Prevention, the Food and Drug Administration, medical societies and others, which could take months.

Although the C.D.C. would prefer that doctors wait for further studies, more probably will prescribe it now that this study is out, said Dr. Kevin Fenton, chief of the agency’s AIDS division, so the C.D.C. will soon release suggested guidelines.

The agency will encourage that the drug be prescribed only with close medical supervision and used only with other safe-sex practices, treatment for venereal diseases and counseling.

“The results are encouraging, but it’s not time for gay men to throw away their condoms,” Dr. Fenton said.

AIDS advocacy groups were very excited by the results.

“If you comply with it, this works really well,” said Chris Collins, policy director of amfAR, the Foundation for AIDS Research. “This is too big to walk away from.”

Mitchell Warren, executive director of AVAC, which lobbies for AIDS prevention, called the study “a great day for the fight against AIDS” and said gay men and others at risk needed to be consulted on the next steps.

AIDS experts and the researchers issued several caveats about the study’s limitations.

It was only of gay men and only of one drug combination. More studies, now under way, are needed to see if they duplicate these results and to see whether Truvada also protects heterosexual men and women, prostitutes and drug users who share needles, and whether other drugs will work, too.

There is no medical reason to think the pill would not work in everyone, since it attacks the virus in the blood, rather than in the vaginal wall as a microbicide does.

Different regimens, like taking the pills only when sex is anticipated instead of daily, also need testing.

Also, many men in the study failed to take all their pills, and some clearly lied about it. For example, some who claimed to take them 90 percent of the time had little or no drug in their bloodstreams.

Although the pills caused no major side effects in the study, some men disliked the relatively minor ones, like nausea and headaches. Also, as is common in clinical trials, some stopped bothering once they suspected they might be taking a placebo.
“People have their own reasons,” Mr. Collins said. “People don’t take their Lipitor every day either.”

A major question now is who will pay for the drug.

In the United States, Truvada, made by Gilead Sciences, costs $12,000 to $14,000 a year. In very poor countries, generic versions costs as little as 40 cents a pill.

Globally, only about 5 million of the 33 million people with AIDS are on antiretrovirals, and, in an era of tight foreign-aid budgets, that number is not expected to rise quickly.

Hundreds of millions of Africans, eastern Europeans and Asians are at risk and could benefit from prophylaxis, but that would cost tens of billions of dollars.

If he had the money, Mr. Sidibé of UNAIDS said, he would target high-risk groups like sex workers, gay men, drug users and uninfected people married to infected people.

In this country, insurers and Medicare normally pay for the drugs, and the Ryan White Act covers the cost for the poor — but none of these payers yet have policies on supplying the drugs to healthy people.

One fear some scientists have is that putting more people on the drugs will speed the evolution of drug-resistant strains.

None of the 2,499 participants developed resistance to tenofovir. Three were found to have strains resistant to emtricitabine, but investigators believe all three were infected before the study began, but at levels low enough to have been missed by their first H.I.V. tests.

Because participants were tested monthly and those who got infected were put on triple therapy cocktails, it was unlikely any were on two-drug Truvada long enough to develop drug resistant strains.

Another fear was that the participants would become so fearless that they would stop using condoms, but the opposite effect was seen — they used condoms more often and had fewer sex partners. But that can also be a function of simply being enrolled in a study and getting a steady diet of safe sex advice and free condoms, the investigators said.

The study took place at 11 sites in the United States, South Africa, Brazil, Thailand, Ecuador and Peru. Other trials of pre-exposure prophylaxis have about 20,000 volunteers enrolled around the world. Their results are expected to arrive in a steady stream over the next two years.