

Vaginal Gel Trials Start in Africa

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CAPE TOWN, South Africa (AP) - Researchers in Africa have started what they describe as the largest trials ever held of a vaginal gel that could help women protect themselves against HIV in countries where men are notoriously reluctant to use condoms.

About 10,000 women in South Africa, Uganda, Tanzania and Zambia are expected to take part in the trial of PRO 2000, which could provide a physical barrier that prevents HIV from reaching target cells during sexual intercourse. It is one of a number of microbicide products in various stages of clinical development around the world. The first nine volunteers were enrolled in Johannesburg this week, said Sibongile Walaza of the University of Witwatersrand Reproductive Health Research Unit.

HIV infection is rising more rapidly among women than men in many parts of the world. Half of all adults living with the virus that causes AIDS are female, according to U.N. figures.

In sub-Saharan Africa, home to more than 25 million of the nearly 40 million people infected globally, the figure is nearly 60 percent, with most new infections acquired through heterosexual intercourse. Yet strong taboos exist on the continent against the use of condoms.

"If there is any other mechanism for women to protect themselves using their own power, then that is absolutely critical," Health Minister Manto Tshabalala- Msimang said at a news briefing Thursday.

Other microbicides under development enhance the natural vaginal defense mechanisms by maintaining an acidic pH, kill pathogens by stripping them of their outer covering, or prevent replication of the virus after it has entered the cell.

PRO 2000 has already been tested on small numbers of women to rule out serious side effects. Clinical trials funded by the British government and coordinated by the Clinical Trials Unit of the British Medical Research Council will take place over three to four years in South Africa, Uganda, Tanzania and Zambia.

Researchers hope to enroll 50 new HIV-free participants a month and ensure that all receive proper counseling and clinical monitoring.

The women will be assigned at random to receive a placebo or the microbicide. They will be asked to use it for one year but can drop out at any time if they are unhappy, Walaza said.

The volunteers will all be counseled to continue using a condom during intercourse, she added. But past experience has shown this advice is frequently ignored, so the trial has been designed to determine whether the gel offers additional protection.

UNAIDS welcomed the microbicide trials, which officials said offer some of the best hope of curbing the deadly pandemic in the absence of a vaccine.

The London School of Hygiene and Tropical Medicine has calculated that a microbicide that is 60 percent effective against HIV and used by only 20 percent of women in 73 developing countries over three years could prevent 2.5 million infections.



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“We are very much in favor of this research going forward and it is good to test the product in a real world setting where it is likely to have most application,” said UNAIDS’ chief scientific adviser, Catherine Hankins.

Researchers hope the first generation of microbicides with 50 percent to 60 percent effectiveness will be available over the counter in five years. By 2012, second generation microbicides that are between 70 percent to 90 percent effective could be on the market, the University of Witwatersrand Reproductive Health Unit said.

Male condoms, if used correctly, can reduce the risk of HIV infection to less than 1 percent.