Reformulated Vaginal Microbicide Gel Looks Promising for Rectal Use

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A reformulated vaginal microbicide gel has proved safe and well tolerated in HIV-negative women and men using it rectally. Microbicide Trials Network–sponsored researchers at the National Institutes of Health (NIH) tested a reduced glycerin formulation of a tenofovir 1 percent gel and published their findings in the journal PLOS ONE. This study was the first to reformulate the gel by using less glycerin in hopes of creating a product more amenable to rectal use. Beginning in October 2010, the study included 65 men and women at three sites: the University of Pittsburgh, the University of Alabama at Birmingham and Fenway Health in Boston.

The participants were randomly divided into four groups. Three received one of three different products over the period of one week: the reduced glycerin formulation of tenofovir gel, a placebo gel without tenofovir, or a gel that contained the spermicide nonoxynol-9. The fourth group only received the study's procedures and tests, which included physical and rectal exams, and no gel.

With no significant difference in side effects between groups, 80 percent of the participants reported minor side effects from the gels and 18 percent reported moderate side effects. Ninety-four percent of the participants used the gels daily as directed. Eighty-four percent of the reformulated gel group said they would likely use the gel again, compared with 93 percent of the placebo gel group and 63 percent of those in the nonoxynol-9 group.

The investigators are planning a Phase II trial of the reformulated gel in 186 men who have sex with men and transgender women.

To read the study, click here.

To read a release on the study, click here.

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