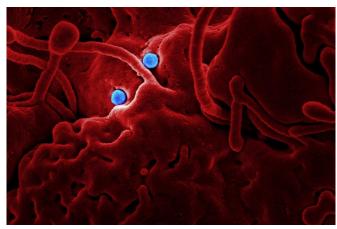


Study: New vaginal film, MB66, is safe

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While a number of topical products designed to reduce the occurrence of sexually transmitted infections have been tested with largely disappointing results, researchers at Boston University School of Medicine (BUSM), Alpert Medical School of Brown University and Mapp Biopharmaceutical have now found that MB66, a vaginal film product containing monoclonal antibodies against human immunodeficiency virustype 1 (HIV-1) and herpes simplex viruses types 1 and 2 (HSV-1 and 2), is safe and effective.

HIV-1 and HSV-1 and 2 are relatively common sexually transmitted infections associated with significant illness and sometimes even death. Though <u>antiviral drugs</u> can suppress viral concentrations and dramatically slow disease progression, these infections are incurable. Therefore, considerable effort is being directed toward <u>prevention strategies</u>.

Researchers conducted a Phase 1 clinical trial to assess the safety, acceptability, drug distribution and effectiveness of both single and repeated doses of MB66. The MB66 vaginal film multipurpose prevention product was safe, and well tolerated, both for single dose, as well as

repeated dose application. In addition, effective antibody levels were detected in vaginal secretions up to 24 hours after product use and they significantly inactivated both HIV-1 and HSV-2 in laboratory tests. Women who participated in the study reported high acceptability and willingness to use the vaginal film with 8 out of ten women reporting they would definitely use the product.

"The results of our study indicate that MB66 is safe and acceptable to women. Furthermore, our data showed excellent antiviral protection for at least 24 hours after product insertion, providing evidence that MB66 is a promising multipurpose prevention technology product to protect women against HIV and HSV-2. More clinical trials are needed to ascertain the clinical efficacy and acceptability in atrisk populations. It may be necessary to add more than one anti-HIV antibody to MB66 for optimal efficacy and to avoid HIV escape mutations," said corresponding author Joseph Politch, Ph.D., associate professor of medicine at BUSM.

To date, there are no effective vaccines to prevent HIV or HSV transmission. Condoms are safe and effective when used consistently and correctly but are generally perceived as a barrier to intimacy and sexual pleasure, and have relatively low acceptability among both men and women. Therefore, there is a need for products like MB66 that can provide protection on demand if used as a vaginal film or longer lasting protection in the form of a vaginal ring. These products will also allow women to have control over their sexual health.

These findings appear online in *PLOS Medicine*.

Provided by Boston University School of Medicine

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