

Animal study provides first evidence that gel can prevent multiple virus transmission in vagina/rectum

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Population Council scientists and their partners have found that their proprietary microbicide gel is safe, stable, and can prevent the transmission of multiple sexually transmitted infections (STIs) in both the vagina and rectum in animals: HIV, herpes simplex virus 2 (HSV-2), and human papillomavirus (HPV). The USAID-funded study also provides the first data that the gel is effective against multiple strains of HIV, and has a window of efficacy in the vagina against all three viruses of at least eight hours prior to exposure. A Phase 1 safety trial of the gel is set to begin enrollment in May 2014.

These findings were published today in *PLOS ONE* in an article entitled "A Potent Combination Microbicide that Targets SHIV-RT, HSV-2 and HPV."

The gel, known as MZC, contains two potent antiviral agents: MIV-150 and zinc acetate. MIV-150 is an enzyme inhibitor that prevents HIV-infected cells from producing new virus, and zinc acetate is an antiviral agent with known activity against HIV and HSV-2. These compounds are mixed in a base of carrageenan, a compound derived from seaweed that has also been shown to have potent activity against HPV. Infection with HSV-2 or HPV is associated with increased risk of HIV infection. Microbicides that target HIV, HSV-2, and HPV may more effectively limit HIV transmission than those that target HIV alone.



In this study, Council scientists and their partners used macaque and mouse models to examine whether MZC gel could prevent the vaginal and rectal transmission of SHIV-RT, HSV-2, and HPV. SHIV-RT is a human/simian immunodeficiency chimeric virus combining the HIV reverse transcriptase (RT) within SIV (the monkey version of HIV). MIV-150 and zinc acetate inhibit HIV-RT via different mechanisms of action. Preclinical testing in animals is required by the FDA and is important to ensure the highest level of safety and to build the evidence base for potential efficacy in humans.

"It is the versatility of MZC that makes it a desirable microbicide candidate," said José A. Fernández Romero, a scientist at the Population Council and corresponding author of the paper. "It is effective against multiple viruses, can be used in both the vagina and the rectum, and retains its efficacy in the vagina over an extended period of time. In addition to the gel, we are also exploring sustained-release intravaginal rings and on-demand film-based delivery systems for MZC. There is a growing demand for microbicides that prevent multiple STIs, and we are committed to ensuring that women and men have options when choosing what works most effectively for their own protection."

More information: Kizima L, Rodríguez A, Kenney J, Derby N, Mizenina O, et al. (2014) A Potent Combination Microbicide that Targets SHIV-RT, HSV-2 and HPV. *PLoS ONE* 9(4): e94547. <u>DOI:</u> <u>10.1371/journal.pone.0094547</u>

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