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Prototypes of a novel vaginal ring design being put to the test in a study that will inform final design of a dual-purpose ring for prevention of both HIV and unplanned pregnancy

Study now enrolling in US; other sites are in South Africa and Zimbabwe

PITTSBURGH – March 21, 2024 – Researchers who are developing a dual-purpose vaginal ring to protect women against both HIV and unplanned pregnancy for a month at a time have begun a study to evaluate prototypes of the ring among women in the United States, South Africa and Zimbabwe, the results of which will help determine the actual product to be tested in the first clinical trial.

The ring's design – with its two cassette-like compartments – is distinctly different from other rings that have either been approved or evaluated in previous clinical trials. Researchers designed the ring in this way as a low-cost, easy-to-manufacture platform for the delivery of two active drugs at different rates. One cassette would contain a non-antiretroviral (non-ARV) agent – an antiviral peptide that blocks viruses from attaching to, penetrating and infecting healthy cells in the body. The other would contain a non-hormonal contraceptive called a soluble adenylyl cyclase (sAC) inhibitor that impedes the movement of sperm and its ability to penetrate and fertilize eggs.

The prototype rings being evaluated in the current study are placebo rings containing no active drug.

The study is being conducted by [MATRIX](#), a United States Agency for International Development (USAID)-funded project focused on the early research and development of innovative HIV prevention products for women, including the non-ARV/non-hormonal contraceptive dual-purpose vaginal ring, which is being developed by the Oak Crest Institute for Science based in Monrovia, Calif.

[MATRIX-003](#) is designed to collect data on the acceptability, usability and safety of two placebo rings (with no active drug) when used for a month at a time. While they are of the same size (56mm, or 2.2", in diameter, and 6.5mm, or ¼", thick) and design, they differ slightly in their flexibility and stiffness. The study will help determine what women like or dislike about each of the rings and which of the two they find more comfortable to use and easier to insert and remove. MATRIX-003 will also assess sexual partners' attitudes toward and experiences with the vaginal ring, particularly within the context of sex. The overall goal of the study is to inform the final design of the ring to be evaluated in clinical trials moving forward, including a first-in-human trial of the ring containing both active ingredients.

MATRIX-003 will enroll 100 HIV-negative women as well as 30 sexual partners at five sites – three in South Africa (the Aurum Institute, Wits RHI and the Centre for the AIDS Programme of Research in South Africa, or CAPRISA) and one each in the United States (based at the University of Pittsburgh and Magee-Womens Research Institute, or MWRI) and Zimbabwe (Harare Health and Research Consortium, or HHRC). The U.S. site has already begun to enroll participants.

"A single product offering protection against both HIV and unwanted pregnancy would be attractive option for many women, perhaps especially so for African women. For the dual-purpose ring being developed under MATRIX, this study is a critically important first step," noted Kathryn Mngadi MBChB, MATRIX-003 protocol co-chair and investigator of record at the Aurum site in Tembisa, South Africa.

"We learned a lot from the studies we conducted of the dapivirine vaginal ring. Despite women's first impressions, they actually took to using the ring. The ring we are evaluating in the MATRIX-003 study is quite different, and no doubt, we will gain much insight from the women who participate in this study," added Krishnaveni (Surina) Reddy, MMedSci, protocol co-chair and an investigator at the Wits RHI site in Johannesburg.

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Women who enroll in the study will use both prototype placebo rings, each for approximately four weeks. Which placebo ring women use first will be determined by randomization. With each ring, women will be asked to abstain from vaginal sex for the first two weeks of use and from use of all vaginal products throughout the duration of the study. Women will insert the rings themselves in the clinic with study staff providing guidance and instructions. As part of the study, participants will undergo physical and pelvic exams and different laboratory tests and procedures and be asked questions about their experience and likes and dislikes with ring use. Approximately 30 participants will also be asked to participate in an in-depth interview at the end of the study so that the study can gain deeper insight into women's experience with and views about the ring.

The study is anticipated to take approximately one year to conduct, with results early 2025. The first Phase 1 study of the vaginal ring containing active drug would likely be launched later that same year.

Vaginal rings as a drug-delivery platform have been most commonly used for contraception, the most notable example being the NuvaRing, which is available in multiple countries world-wide. The monthly dapivirine vaginal ring, which has been approved for use in several African countries, is currently the only ring for use as HIV prevention. A 90-day dapivirine and levonorgestrel ring is being evaluated for use as a dual-purpose product to prevent both HIV and unplanned pregnancy. Other vaginal rings, including dual-purpose and multi-purpose rings are in development as well.

According to UNAIDS, women and girls accounted for 63 percent of all new HIV infections in sub-Saharan Africa in 2022, versus 46 percent globally. In much of Africa, daily oral PrEP is the only biomedical prevention method available, and daily pill-taking has been especially challenging for adolescent girls and young women. Both the monthly dapivirine ring and cabotegravir long-acting injectable (CAB-LA) have been recommended by the World Health Organization and approved for use in several African countries, though neither method is yet to be made widely available. Even so, women have different preferences and needs, and at different times in their lives, which is why additional options are needed.

MATRIX is a five-year program funded by USAID in 2021 that aims to expedite the research and development of HIV prevention products for women – including products designed to protect against both HIV and pregnancy – that in addition to being safe and effective, will be acceptable, affordable, scalable and deliverable in the settings where they are needed most. MATRIX activities are focused on the early research and development of products, which involves both pre-clinical research and the first clinical trials of products. Through its North-South partnerships, MATRIX also aims to strengthen the capacity of African investigators to facilitate full and sustainable ownership of this work into the future.

MATRIX is being implemented by Magee-Womens Research Institute (MWRI) in collaboration with partner organizations based in Kenya, South Africa, the United States and Zimbabwe. Leading the project is Sharon Hillier, Ph.D., of MWRI and the University of Pittsburgh School of Medicine, with Thesla Palanee-Phillips, Ph.D., from the Wits RHI and University of Witwatersrand, South Africa, serving as deputy director.

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To learn about MATRIX go to www.matrix4prevention.org. Click [here](#) to read a QA about the dual-purpose ring and MATRIX-003 study. Additional information about MATRIX-003 can also be found at <https://www.matrix4prevention.org/activity-hubs/clinical-trials/matrix-003>. MATRIX was established through the generous support of the American people through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the U.S. Agency for International Development (USAID).
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