Medicines Control Authority of Zimbabwe

Clinical Trials Registry

PUBLIC TITLE/ACRONYM	OCIS Placebo Ring Study
Scientific Title	MATRIX-003 Trial to Assess Acceptability and Safety of Two Placebo Intravaginal Ring (IVR) Designs

Primary Sponsor Details

Sponsors *	MATRIX: A USAID Project to Advance the Research and Development of Innovative HIV Prevention Products for Women

Secondary Sponsor Details

Contact for Public Queries

Name *	Petina Musara
Designation *	Zengeza CRS Coordinator
Email *	pmusara@uz-ctrc.org
Phone number *	+263 772471684
Postal Address*	HHRC, 4 Ascot Rd, Avondale West, Harare
Affiliation	Harare Health and Research Consortium

Contact for Scientific Queries

Name *	Nyaradzo M Mgodi
Designation *	Investigator of Record
Email *	nmgodi@uz-ctrc.org
Phone number *	+263772264616
Postal Address*	HHRC, 4 Ascot Rd, Avondale West, Harare
Affiliation	Harare Health and Research Consortium

Countries of Recruitment *

United States of America, South Africa, and Zimbabwe.

Source of Funds	USAID
Health Condition(s) or Problem(s) Studied *	HIV Prevention Trial
Medicine Name *	Placebo Intravaginal ring
Quantity of medicine required *	20

7.0 PRINCIPAL INCLUSION CRITERIA *

1) Aged 18 to 45 years (inclusive) at Screening, verified per site SOP.
2) Assigned female sex at birth.
3) Able and willing to provide written informed consent to be screened for and enrolled in MATRIX-003 in one of the study languages
4) Able and willing to provide adequate contact/locator information
5) Able and willing to comply with all protocol requirements, including:
• Abstaining from other intravaginal products or practices for the duration of the study (as specified in Section 6.7).
• Abstaining from penetrative vaginal intercourse (i.e., oral-, digital-, and penile-penetration) for the first 14 days of each product use period.
• Refraining from participation in other research studies involving drugs, medical devices, vaginal products, or vaccines starting 2 weeks before the Screening Visit and for the duration of the study, or in observational or qualitative studies for the duration of the study, unless approved by the Protocol Safety Review Team (PSRT).
• Reliable access to a private phone for scheduled phone contacts.
6) HIV-uninfected based on testing performed at Screening and Enrolment (per protocol algorithm in Appendix II).
7) Per participant report, must be either not currently sexually active or in a mutually monogamous relationship with only one partner who is not known to be HIV positive or to currently have a sexually transmitted infection (STI).
8) Negative urine pregnancy test at Screening and Enrolment.
9) Participants over the age of 21 (inclusive) must have documentation of a Grade 0 Pap smear within the past 3 years prior to Enrolment, or a Grade 1 Pap smear at Screening with no treatment required, per the Female Genital Grading
7
Table for Use in Microbicide Studies Addendum 1 (Dated November 2007) to the DAIDS Table for Grading Adult and Pediatric Adverse Events, Corrected Version 2.1, July 2017.
10) Protected from pregnancy starting at least 2 weeks before Screening and continuing for the duration of study participation by an effective contraceptive method as confirmed by site SOP; effective methods include:
• Hormonal methods except vaginal rings
• Copper intrauterine device (IUD)
• Sterilization of participant or (if applicable) sterilization of monogamous partner
• Correct and consistent condom use at study entry, and agrees to use site-provided condoms during study (for US site only)

7.1 PRINCIPAL EXCLUSION CRITERIA *

Exclusion Criteria
1) Per participant report at Screening and Enrollment, intends to do any of the following during the study participation period:
• Become pregnant.
• Breastfeed.
• Relocate away from the study site.
• Travel away from the study site for a time period that would interfere with product resupply and/or study participation.
2) Positive HIV test at Screening or Enrollment.
3) Positive test for Trichomonas vaginalis (TV), Neisseria gonorrhea (GC), Chlamydia trachomatis (CT), or Treponema pallidum (Syphilis) at Screening and (per participant report) treated for potential STI within past 12 months.
4) Diagnosed with urinary tract infection (UTI), pelvic inflammatory disease (PID), or reproductive tract infection (RTI) requiring treatment per WHO guidelines at Enrollment.
5) Clinically apparent Grade 2 or higher pelvic exam finding per the DAIDS Table for Grading Adult and Pediatric Adverse Events, Corrected Version 2.1, July 2017 and/or Addenda 1
6) Participant report and/or clinical evidence of any of the following:
• Known adverse reaction to silicone (ever).
• Use of diaphragm, NuvaRing, or spermicide for contraception starting 2 weeks prior to Screening through Enrollment.
• Use of any of the following in the past 12 months: stimulants (cocaine [including crack], methamphetamine, or non-physician prescribed pharmaceutical-grade stimulants), or inhaled nitrates, or illicit injection drug use of any kind.
• Prior use of post-exposure prophylaxis (PEP) or oral pre-exposure prophylaxis (PrEP) (including FTC/TDF) in the past 4 weeks or any prior use of long-acting systemic PrEP (including cabotegravir or islatravir).
• Antibiotic, steroid, or antifungal (oral or intravaginal) therapy within 14 days of Enrollment.
• Hysterectomy.
• Gynecologic or genital procedure (e.g., tubal ligation, dilation and curettage, piercing, IUD insertion or removal, colposcopy) within 21 days prior to Enrollment.
• At Screening or Enrollment, as determined by the Investigator of Record (IoR)/designee, has any significant uncontrolled active or chronic cardiovascular, renal, liver, hematologic, neurologic, gastrointestinal, psychiatric, endocrine, respiratory, immunologic disorder or infectious disease.
7) Has any of the following laboratory abnormalities at Screening:
• Grade 2 or higher Aspartate aminotransferase (AST), alanine transaminase (ALT), creatinine, or Haemoglobin per the DAIDS Table for Grading Adult and Pediatric Adverse Events, Corrected Version 2.1, July 2017.
8) Has any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.

7.2 PRIMARY END POINTS *

Acceptability -
-Proportion of participants preferring each placebo IVR (A or B).
8
-Mean rating of overall satisfaction with using each placebo IVR.

9.0 DESIGN OF THE TRIAL

Type of trial *	Opened

If controlled

Randomised	Yes
Single Blind	No
Double Blind	No
Parallel group	Yes
Cross over	No
Other	Yes
If yes to other, specify	Partially blinded, only the site behavioural team and participants will be blinded
If controlled, specify the comparator	
Other medicinal product(s)	
Placebo	
Other	
If yes to other, specify	
Other	Yes

Expected Number of participants in Zimbabwe *	20
Total enrolment in each site: (if competitive enrolment, state minimum and maximum number per site.) *	20
Total participants worldwide *	100

Time period for the trial *	9 months