Medicines Control Authority of Zimbabwe

Clinical Trials Registry

PUBLIC TITLE/ACRONYM	Annovera Study
Scientific Title	Pilot project to assess acceptability, uptake and continuation of Annovera® Contraceptive vaginal ring over 1 year (13 menstrual cycles) of use among adolescent girls and young women 16-24 years old seeking family planning services in two Mbare clinic

Primary Sponsor Details

Sponsors *	MSF Zimbabwe Mission

Secondary Sponsor Details

Contact for Public Queries

Name *	Mr Farai Machinga
Designation *	PI, Technical Director
Email *	machingaf@gmail.com
Phone number *	+263772101057
Postal Address*	No 1 Swiss Way, Harare Hospital Grounds, Southerton
Affiliation	Zimbabwe National Family Planning Council

Contact for Scientific Queries

Name *	Dr Lisa Haddad
Designation *	Co-PI, Medical Director
Email *	lhaddad@popcouncil.org
Phone number *	+263773031506
Postal Address*	1230 York Avenue, New York
Affiliation	Population Council

Countries of Recruitment *

Zimbabwe

Source of Funds	MSF Zimbabwe Mission
Health Condition(s) or Problem(s) Studied *	Contraception Effectiveness
Medicine Name *	Annovera Contraceptive Vaginal Ring
Quantity of medicine required *	200

7.0 PRINCIPAL INCLUSION CRITERIA *

Female participants must meet all criteria listed below to be eligible for inclusion in the study:

- Ages 16 through 24 years old (inclusive) at screening
- At risk for pregnancy and desiring to initiate a new contraceptive method or change from one they are currently using
- Able and willing to provide informed consent
- Able and willing to provide adequate locator information
- Own or have access to a mobile phone so study staff can call for check-ins and remote follow-up visits
- In the opinion of the Site PI or designee, able and willing to comply with the protocol and all study procedures

Providers at the study clinics will be educated about the study to identify AGYW who might be eligible and interested in participating. Among the providers at the clinics there are Peer Educators who interact with other peers in the community creating awareness on health-related issues and where the peers can get services. These peers will share information about the study and refer those interested to the Edith Opperman and Matapi clinics. Any recruitment materials developed will be approved by the Population Council IRB, the MSF ERB, and Medical Research Council of Zimbabwe (MRCZ), Medicines Control Authority of Zimbabwe (MCAZ) and the Research Council of Zimbabwe (RCZ) relevant local ethics committees and translated into Shona (the most common local language) prior to use.

7.1 PRINCIPAL EXCLUSION CRITERIA *

Females who meet any of the following criteria will be excluded from the study:

- Pregnant at screening or enrollment
- Trying to become pregnant or desire pregnancy within the next year
- Currently breastfeeding at screening (per self-report)
- Within 6 weeks postpartum and not breastfeeding at screening (per self-report)
- BMI>29
- Migraine with aura
- Active smoking
- Known hypersensitivity to estrogens, progestins or any of the components of Annovera
- Known contraindication to combined hormonal contraception, based on WHO eligibility criteria (Categories 3 and 4):
    - High risk of arterial or venous thrombotic disease:
        - Have current or history of deep vein thrombosis or pulmonary embolism
        - Have current or history of cerebrovascular disease
        - Have coronary artery disease
        - Have ischemic heart disease
        - Have thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation)
        - Have inherited or acquired hyper-coagulopathies
        - Have uncontrolled hypertension or hypertension with vascular disease
        - Are immobilized for long periods of time
        - Planning on undergoing major surgery
        - Have systemic lupus erythematosus with positive or unknown antiphospholipid antibodies
    - Known condition where steroid hormones are contraindicated
    - Have current or history of breast cancer or other estrogen- or progestin-sensitive cancer.
    - Have liver tumors, acute hepatitis, or severe (decompensated) cirrhosis
    - Symptomatic gallbladder disease
- Use of medications that are contraindicated or is believed to have a drug-drug interaction with Annovera
- History of undiagnosed abnormal genital bleeding reported at screening
- Undiagnosed vaginal discharge, vaginal lesions, or pelvic infections
- Symptomatic infections can be treated, and participants can enroll following resolution of symptoms
- Any other condition the clinician feels would jeopardize the health and wellbeing of the participant

7.2 PRIMARY END POINTS *

The primary endpoint is the proportion of AGYW who are adherent to the Annovera regimen, based on the questionnaires. The questionnaire was adapted from the Annovera Phase 3 acceptability study.

- Remembering to insert and remove the ring on schedule
- Number of times in the first three weeks of the cycle the subject removed the ring for more than 2 hours
- Responses to questions on ease of use
- Expulsions/feeling the ring
- Effect on sexual activity

We will also evaluate the proportion of women reporting they are “highly satisfied” or “satisfied” with Annovera.

9.0 DESIGN OF THE TRIAL

Type of trial *	Opened

If controlled

Randomised	
Single Blind	
Double Blind	
Parallel group	
Cross over	
Other	
If yes to other, specify	
If controlled, specify the comparator	
Other medicinal product(s)	
Placebo	
Other	
If yes to other, specify	
Other	

Expected Number of participants in Zimbabwe *	200
Total enrolment in each site: (if competitive enrolment, state minimum and maximum number per site.) *	maximum 150 minimun 50
Total participants worldwide *	200

Time period for the trial *	April 2023 to December 2024