Medicines Control Authority of Zimbabwe

Clinical Trials Registry

PUBLIC TITLE/ACRONYM	R34 DPP Clinical Study-A crossover acceptability study assessing a DPP capsule for HIV and pregnancy prevention
Scientific Title	A randomized, crossover study to evaluate the acceptability of an over-encapsulated dual prevention pill (DPP capsule) containing pre-exposure prophylaxis (PrEP) and a combined oral contraceptive (COC) pill versus two separate tablets (PrEP and COC) among

Primary Sponsor Details

Sponsors *	National Institutes of Mental Health (NIMH), US National Institutes of Health (NIH); Children's Investment Fund Foundation (CIFF)

Secondary Sponsor Details

Contact for Public Queries

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Countries of Recruitment *

South Africa and Zimbabwe

Source of Funds	The Population Council, Inc.
Health Condition(s) or Problem(s) Studied *	HIV and Contraceptives
Medicine Name *	DPP Capsule (TDF 300mg/FTC 200mg/ EE 30mcg/ LNG 150mcg Over-encapsulated dual prevention pill (DPP
Quantity of medicine required *	Oral Prep (TDF 300mg/FTC 200mg) COC (EE 30mcg/LNG 150mcg)

7.0 PRINCIPAL INCLUSION CRITERIA *

- Cisgender female aged 16 through 24 years old (inclusive) at Screening.
- Able and willing to provide informed consent per site SOPs. [If under the legal age of consent (18 years old) and/or an unemancipated minor, be able to provide informed assent and obtain parental or guardian permission/consent, to be screened for and to enrol in the study]
- Fluent (speaking) Shona and/or English
- Able and willing to provide adequate locator information, as defined in site SOPs.
- Able and willing to comply with all study procedures.
- Post-menarche, per participant report at Screening.
- Sexually active, defined as having had penile-vaginal sex with a male within the 3 months before Screening (per self-report)
- At moderate to high risk of HIV infection based on modified VOICE risk score[87, 88]
- Considers herself to be at moderate to high risk of HIV acquisition based on self-assessment.
- Currently using COCs for contraception, and has been using them for at least 3 months prior to Screening
- HIV-negative per rapid test at Screening and Enrolment per site-specific SOP
- Negative pregnancy test at Screening and Enrolment
- Negative for chlamydia, gonorrhea, trichomoniasis, and syphilis at Screening; women who test positive at Screening may be treated and enrolled
- Hepatitis B surface antigen and Hepatitis C negative per blood test at Screening
- Normal estimated creatinine clearance (eCrCl) ≥ 60 ml/min per blood test at Screening

7.1 PRINCIPAL EXCLUSION CRITERIA *

- Positive test for HIV at Screening or Enrolment
- Positive pregnancy test at Screening or Enrolment
- Currently using emtricitabine (FTC) or tenofovir (TDF) at Screening (per self-report)
- Use of PEP within 3 months of Screening (per self-report).
- Intends to become pregnant within the next 12 months.
- Intolerance, SAE or laboratory abnormality associated with PrEP use in the past.
- Breast feeding < 6 months postpartum (per self-report).
- < 6 weeks (<=42 days) postpartum and not breastfeeding (per self-report).
- History of thrombophlebitis or thromboembolic disorders at Screening (per self-report or medical records)
- History of cerebro-vascular or coronary artery disease reported at Screening
- History of carcinoma of the breast or other estrogen-dependent neoplasia reported at Screening
- History of undiagnosed abnormal genital bleeding reported at Screening
- Benign or malignant liver tumor reported at Screening
- Prolonged immobilization
- Known thrombogenic mutation\Complicated valvular disease
- Ischemic heart disease
- Systemic lupus erythematosus with positive or unknown antiphospholipid antibodies
- Migraines with aura, if under 35 years old
- Migraines without aura, if 35 years and older
- History of smoking or current smoker, if 35 years and older
- Diabetes with nephropathy, retinopathy or neuropathy
- Diabetes for > 20 years
- Symptomatic gall bladder disease
- Severe Cirrhosis
- Liver tumor
- Estimated creatinine clearance (eCrCl) < 60 ml/min per Screening blood test
- Any other condition the clinician feels would jeopardize the health and wellbeing of the participant

7.2 PRIMARY END POINTS *

Preference

Proportion of women who prefer the DPP capsule versus 2 separate tablets after using each regimen for three 28-day cycles.

Acceptability

Acceptability scores by regimen and overall, per a quantitative acceptability questionnaire.

9.0 DESIGN OF THE TRIAL

Type of trial *	Controlled
If controlled	
Randomised	Yes
Single Blind	
Double Blind	
Parallel group	Yes
Cross over	Yes
Other	
If yes to other, specify	
If controlled, specify the comparator	2 separate tablets containing TDF 300mg /FTC 200mg and EE 0.03mg/LNG15mg
Other medicinal product(s)	
Placebo	
Other	
If yes to other, specify	
Other	

Expected Number of participants in Zimbabwe *	30
Total enrolment in each site: (if competitive enrolment, state minimum and maximum number per site.) *	N/A
Total participants worldwide *	60

Time period for the trial *	3 Years