Medicines Control Authority of Zimbabwe

Clinical Trials Registry

PUBLIC TITLE/ACRONYM	ENGAGE
Scientific Title	A Phase II Acceptability Study of Oral emtricitabine/tenofovir alafenamide (F/TAF) vs emtricitabine/tenofovir disoproxil fumarate (F/TDF) for the Prevention of HIV Acquisition in Adolescent Girls and Young Women (AGYW)

Primary Sponsor Details

Sponsors *	CONRAD

Secondary Sponsor Details

Contact for Public Queries

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Affiliation	

Countries of Recruitment *

South Africa and Zimbabwe.

Source of Funds	USAID and Gilead
Health Condition(s) or Problem(s) Studied *	HIV
Medicine Name *	emtricitabine/tenofovir disoproxil fumarate (F/TDF, Truvada®) and emtricitabine/tenofovir alafenamide (F/TAF, Descovy®)
Quantity of medicine required *	330 bottles of Descovy and 330 bottles of Truvada

7.0 PRINCIPAL INCLUSION CRITERIA *

1. Female, age 15 to 24 years (inclusive), ages 16-24 in Zimbabwe
2. Literate, per local standards, to English and/or local language
3. In general good health, per participant reported medical history and investigator judgement, without any clinically significant systemic disease including but not limited to: significant liver disease or hepatitis, gastrointestinal disease, kidney disease, osteoporosis or bone disease (e.g., pathologic bone fractures not related to trauma), autoimmune disorder, and diabetes.
4. Willing to give voluntary informed consent and sign an informed consent form
5. Women at potential risk of acquiring HIV
6. Willing and able to comply with protocol requirements, including swallowing tablets
7. Total body weight ≥35 kg
8. eGFR or Creatinine Clearance of ≥60 mL/min according to the Cockcroft-Gault formula
9. Have not used oral PrEP ever (PrEP naïve) or in the past 6 months
10. If pregnant, must be considered a healthy, singleton pregnancy, considered low risk by local standard of obstetric practices

7.1 PRINCIPAL EXCLUSION CRITERIA *

1. Positive test for HIV or HBsAg
2. Signs or symptoms of acute HIV infection
3. Use of ARV PrEP within the past 180 days
4. History of sensitivity or allergy to any component of the study drug products
5. Systemic use in the last two (2) weeks or anticipated use during the course of the study of any restricted products, as outlined in Section 8.2 of the protocol
6. Known current drug or alcohol abuse which could impact study compliance
7. Grade 2 or higher laboratory abnormality, per the Division of AIDS, National Institute of Allergy and Infectious Disease (DAIDS) Table for Grading the Severity of Adverse Events, or clinically significant laboratory abnormality as determined by the clinician or study PI
8. Abnormal finding on laboratory or physical examination or a social or medical condition in the volunteer, which, in the opinion of the investigator, would make participation in the study unsafe or would complicate interpretation of data
9. Participation in any other investigational trial with use of a drug/device within the last 30 days or planned participation in any other investigational trial with use of a drug/device during the study
10. History of pathological bone fracture
11. Pregnant <33 weeks gestation (must have received antenatal care); breastfeeding with infant >6 months old

7.2 PRIMARY END POINTS *

Acceptability: Discontinuation rate; attendance at follow-up visits; responses to quantitative assessments collected through questionnaires, and qualitative data collected through in-depth interviews (IDIs) and focus group discussions (FGDs)

9.0 DESIGN OF THE TRIAL

Type of trial *	Controlled
If controlled	
Randomised	Yes
Single Blind	No
Double Blind	No
Parallel group	Yes
Cross over	No
Other	Yes
If yes to other, specify	This two-arm open label acceptability study will examine acceptability of, and adherence to, standard oral PrEP once daily dosing regimen of F/TDF and an investigational once daily dosing oral PrEP regimen of F/TAF under standard of care counselling.
If controlled, specify the comparator	Truvada (emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg)
Other medicinal product(s)	No
Placebo	No

Other	No
If yes to other, specify	
Other	Yes

Expected Number of participants in Zimbabwe *	110
Total enrolment in each site: (if competitive enrolment, state minimum and maximum number per site.) *	110
Total participants worldwide *	330

Time period for the trial *	1 year