Medicines Control Authority of Zimbabwe

Clinical Trials Registry

PUBLIC TITLE/ACRONYM	OPTImising Metabolic management on Integrase based ART (OPTIMAR)
Scientific Title	A Phase III/IV factorial randomised double-blind trial to compare the addition of dapagliflozin versus placebo, and rosuvastatin/ezetimibe versus pitavastatin, in patients with HIV on integrase strand transfer inhibitor-based antiretroviral therapy with e

Primary Sponsor Details

Sponsors *	University of New South Wales

Secondary Sponsor Details

Contact for Public Queries

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Affiliation	

Contact for Scientific Queries

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Postal Address*	Department of Medicine, University Of Zimbabwe Faculty
Affiliation	

Countries of Recruitment *

Australia, United Kingdom, Thailand, Malaysia, India, South-Africa, Nigeria, Zimbabwe, Uganda and Argentin

Source of Funds	University of New South Wales
Health Condition(s) or Problem(s) Studied *	Research question to be addressed by this proposal is to to examine the feasibility, benefits and risks of adding a sodium-glucose cotransporter 2 (SGLT2) inhibitor (dapagliflozin 10 mg) to INSTI-based ART in PWH with elevated metabolic risk (in OPTIMAR as determined by weight gain/obesity after commencing INSTI therapy). SGLT2 inhibitors have been shown to reduce major adverse cardiovascular events (MACE) in other high-risk groups, but to date, have not been trialed in PWH.
Medicine Name *	Dapagliflozin,Pitavastatin,Rosuvastatin,Ezetimibe
Quantity of medicine required *	Dapagliflozin 10mg,Pitavastatin4mg,Rosuvastatin10mg,Ezetimibe10mg

7.0 PRINCIPAL INCLUSION CRITERIA *

Inclusion criteria

1. 1. 40-75 years and at least one of the following risk factors:

- a. BMI > 7% increase or > 5kg weight gain since INSTI commencement, or
- b. BMI ≥ 30 kg/m_2

2.BMI ≥18 kg/m_2 prior to INSTI commencement

3.Currently taking INSTI-based ART

4.Sustained virologic response, defined as viral load <200 copies/mL for at least 12 months

5.Current CD4 >250 cells/mm_3

6.Informed consent for trial participation

7.1 PRINCIPAL EXCLUSION CRITERIA *

Exclusion criteria

1.Currently taking a protease inhibitor
2. Indicated to take or already taking high intensity statin
3. eGFR< 30 ml/min/1.73m2
4. Currently taking an SGLT-2 inhibitor or GLP-1 agonist
5. Absolute contraindication or absolute indication to SGLT2 inhibitor therapy
6. Absolute contraindication to pitavastatin, rosuvastatin, ezetimibe or combination of rosuvastatin/ezetimibe
7. Pregnant or breast feeding
8. Severe hepatic impairment (Child Pugh B or C)
9. Participants receiving any excluded/contraindicated medication
10. Participants who are enrolled into an additional interventional study.
11. Expected inability or unwillingness to participate in study procedures.
12. In the opinion of the investigator, participation in a trial is not in the best interest of the patient.

7.2 PRIMARY END POINTS *

Mean reduction change in body weight (kg) across treatment arms at 24 weeks, defined as absolute body weight change.

Mean change in LDL as absolute change from baseline to 24 weeks across treatment arms

9.0 DESIGN OF THE TRIAL

Type of trial *	Controlled

If controlled

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

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.) *	30(Maximum subject enrolment may be adjusted by the Sponsor based on interim global recruitment reviews during the trial)
Total participants worldwide *	300

Time period for the trial * January 2025 to June 2027