Medicines Control Authority of Zimbabwe

Clinical Trials Registry

PUBLIC TITLE/ACRONYM	Pharmacokinetic study of a novel DTG/FTC/TAF dose ratio for children
Scientific Title	Pharmacokinetic study of an optimized dose ratio of dolutegravir/emtricitabine/tenofovir alafenamide fumarate: expediting a UNIVERSAL first line regimen for all children living with HIV in Africa

Primary Sponsor Details

Sponsors *	Fondazione Penta ETS

Secondary Sponsor Details

Contact for Public Queries

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Countries of Recruitment *

Zimbabwe **and Uganda.**

Source of Funds	: Fondazione Penta ETS
Health Condition(s) or Problem(s) Studied *	HIV infection
Medicine Name *	DTG 10 mg dispersible tablets FTC/TAF 15/1.88 mg dispersible tablets DTG 50 mg film coated tablets FTC/TAF 200/25 mg film coated tablets
Quantity of medicine required *	The study drugs will be ordered from the sponsor intermittently as the study progresses. The quantities ordered will be determined by the participant recruitment rate and duration of follow-up.

7.0 PRINCIPAL INCLUSION CRITERIA *

Age between 28 days to ≤10 years old
- Weighing ≥3 to <25 kg
- Confirmed HIV-1 infection (local, molecular methods)
- A parent or legal guardian is willing and able to give informed consent on behalf of the child as per national legislation and willing to adhere to the protocol
- Participant is willing to give informed assent if the trial site clinician deems them old enough and able to understand the age- appropriate information about participation in the study
- Girls who have reached menarche must have a negative pregnancy test at screening
- Subject is willing to start DTG/FTC/TAF regimen in the novel dose ratio for HIV treatment
- Subjects already on a DTG-based antiretroviral therapy (ART) regimen should be virologically suppressed, or within 6 months after start treatment, at screening

7.1 PRINCIPAL EXCLUSION CRITERIA *

- History or presence of known allergy to DTG, FTC or TAF

- Alanine aminotransferase (ALT) ≥5 times the upper limit of normal (ULN), OR ALT ≥3xULN AND bilirubin ≥2xULN
- Patients with severe hepatic impairment or unstable liver disease (as defined by the presence of ascites, encephalopathy, coagulopathy, hypoalbuminaemia, oesophageal or gastric varices, or persistent jaundice), known biliary abnormalities (with the exception of Gilbert's syndrome or asymptomatic gallstones)

- Current or anticipated need for TB therapy during the study
- Use of rifampicin-based therapy within 4 weeks before start trial - Presence of comedication known to interact with trial medications
- Known resistance for INSTI or NRTI for naïve patients (see appendix V)
- Clinician concern for significant poor adherence in the past

7.2 PRIMARY END POINTS *

1. Primary endpoints for DTG:
   - Geometric mean plasma concentration 24h after observed intake (C24)
   - Percentage of individual plasma C24 concentrations below the 90% effective concentration (EC90) (0.32 mg/L)
   - Geometric mean DTG plasma maximum concentration (Cmax), and the area under the concentration-time curve over the dosing interval (AUC0-24h)
2. Primary endpoints for FTC/TAF:
   - Geometric mean plasma FTC, TAF, TFV C24 (Clast for TAF), Cmax, and AUC0-24h

9.0 DESIGN OF THE TRIAL

Type of trial *	Opened
If controlled	
Randomised	
Single Blind	
Double Blind	
Parallel group	
Cross over	
Other	Yes
If yes to other, specify	UNIVERSAL1 is an interventional, phase II, multicenter, single-arm study. A total of 50 children will be enrolled over approximately 9 months. A short-term follow-up of 24 weeks will be conducted. All children enrolled will be participating in the intens
If controlled, specify the comparator	
Other medicinal product(s)	No
Placebo	No
Other	No
If yes to other, specify	

Other Yes

Expected Number of participants in Zimbabwe *	25
Total enrolment in each site: (if competitive enrolment, state minimum and maximum number per site.) *	N/A
Total participants worldwide *	50

Time period for the trial * 15 months in total (9 months enrolment/study accrual)