Medicines Control Authority of Zimbabwe

Clinical Trials Registry

PUBLIC TITLE/ACRONYM	BREATHER+
Scientific Title	A randomized open-label 2-arm, 96-week trial evaluating the efficacy, safety and acceptability of short cycle (five days on, two days off) dolutegravir/tenofovir-based triple antiretroviral therapy (ART) compared to daily dolutegravir/tenofovir-based trip

Primary Sponsor Details

Sponsors *	University College London (UCL)

Secondary Sponsor Details

Contact for Public Queries

Name *	Dr. Mutsawashe Filda Bwakura-Dangarembizi
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Name *	Dr. Mutsawashe Filda Bwakura-Dangarembizi
Designation *	Principal Investigator
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Affiliation	UZCRC

Countries of Recruitment *

Zimbabwe

South Africa

Uganda

Kenya

Source of Funds	Funded
Health Condition(s) or Problem(s) Studied *	A randomized open-label 2-arm, 96-week trial evaluating the efficacy, safety and acceptability of short cycle (five days on, two days off) dolutegravir/tenofovir-based triple antiretroviral therapy (ART) compared to daily dolutegravir/tenofovir-based triple ART in virologically suppressed HIV-infected adolescents aged 12 to 19 years of age in sub-Saharan Africa.

Medicine Name *	Dolutegravir with Tenofovir and Lamivudine or Emtricitabine
Quantity of medicine required *	1 500

7.0 PRINCIPAL INCLUSION CRITERIA *

1. HIV-1-infected

2. Aged 12 to 19 years

3. Aware of HIV status

4. On ART for ≥1 year, with no previous regimen change for treatment failure

5. On ART consisting of DTG, tenofovir and lamivudine/emtricitabine for ≥1 month prior to screening

6. Virologically suppressed with all HIV-1 RNA viral loads <50copies/mLa in the last 12 months up to and including screening. Additionally, there must be one result <50copies/mLa at least 12 months prior to screening and the viral load at trial screening must be <50 copies/mL

7. Girls who are sexually active must be willing to adhere to highly effective methods of contraception

8. Written informed consent provided by participant (if aged 18 to 19 years) and/or carer/legal guardian (if participant aged 12 to 17 years) as appropriate

9. Written informed assent in participants aged 12 to 17 years

7.1 PRINCIPAL EXCLUSION CRITERIA *

1. Females who are pregnant or breastfeeding

2. Females who plan to become pregnant during the trial follow-up or are unwilling to use a highly effective method of contraception for the duration of the trial if sexually active

3. Moderate or High-risk score on the Columbia-Suicide Severity Rating Scale

4. On treatment for any active TB

5. Contraindication to continued receipt of dolutegravir or any formulation of tenofovir, lamivudine/emtricitabine

6. Underlying medical condition that in the opinion of the Investigator precludes participation

7. Previous randomisation in the LATA trial

7.2 PRIMARY END POINTS *

The proportion of participants with confirmed virological rebound, defined as the first of 2 consecutive plasma HIV-RNA ≥50 copies/mL at any time up to the 96-week assessment.

9.0 DESIGN OF THE TRIAL

Type of trial *	Opened

If controlled

Randomised	Yes
Single Blind	No
Double Blind	No
Parallel group	No
Cross over	No
Other	No
If yes to other, specify	
If controlled, specify the comparator	

Other medicinal product(s)	Yes
Placebo	No
Other	No
If yes to other, specify	
Other	No

Expected Number of participants in Zimbabwe *	130
Total enrolment in each site: (if competitive enrolment, state minimum and maximum number per site.) *	130
Total participants worldwide *	460

Time period for the trial *	1 October 2021 - 31 December 2025