Medicines Control Authority of Zimbabwe

Clinical Trials Registry

PUBLIC TITLE/ACRONYM	LATA
Scientific Title	Long-Acting Treatment in Adolescents (LATA): A randomised open-label 2-arm 96-week trial in virologically suppressed HIV-1-positive adolescents aged 12-19 years of age in Sub-Saharan Africa

Primary Sponsor Details

Sponsors *	Medical Research Council (MRC) Clinical Trials Unit (CTU) at University College London (UCL)

Secondary Sponsor Details

Contact for Public Queries

Name *	Dr. Mutsawashe Filda Bwakura-Dangarembizi
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Contact for Scientific Queries

Name *	Dr. Mutsawashe Filda Bwakura-Dangarembizi
Designation *	Principal Investigator
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Countries of Recruitment *

Zimbabwe

Kenya

South Africa

Uganda

Source of Funds	Funded
Health Condition(s) or Problem(s) Studied *	Long-Acting Treatment in Adolescents (LATA): A randomised open-label 2-arm 96 week trial in virologically suppressed HIV-1-positive adolescents aged 12-19 years of age in Sub-Saharan Africa.
Medicine Name *	1. Dolutegravir with Tenofovir and Lamivudine or Emtricitabine 2. Oral Cabotegravir. Oral Rilpivirine. Cabotegravir injection. Rilpivirine Injection.

Quantity of medicine required *	1500

7.0 PRINCIPAL INCLUSION CRITERIA *

1. HIV-1-positive
2. Aged 12-19 years
3. Aware of HIV status
4. Body weight ≥35Kg
5. On ART consisting of 2NRTI and a third agent
6. On ART for ≥1 year with no previous regimen change for treatment failure
7. Virologically suppressed with all HIV-1 RNA viral loads <50copies/mL in the last 12 months up to and including screening. Additionally, there must be one result <50copies/mL at least 12 months prior to screening and the viral load at trial screening must be <50 copies/mL
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
10. Females who are sexually active must be willing to adhere to highly effective methods of contraception

7.1 PRINCIPAL EXCLUSION CRITERIA *

1. Known HIV-2 positive
2. Females who are pregnant or breastfeeding
3. Females who plan to become pregnant during the trial follow-up or are sexually active and are unwilling to avoid pregnancy for the duration of the trial
4. Moderate or high-risk score on the Columbia-Suicide Severity Rating Scale
5. Hepatitis B SAg positive
6. ALT ≥3 x upper limit of normal
7. On treatment for active TB
8. Known contraindication to receipt of dolutegravir, cabotegravir, rilpivirine, emtricitabine/ lamivudine and any formulation of tenofovir
9. Participants determined by the investigator to have a high risk of seizure, including those with unstable or poorly controlled seizure disorder
10. Unwilling or contraindication to receiving injections
11. Contraindication to receiving injectable agents in the buttock area
12. Underlying medical condition (e.g. bleeding disorder; use of warfarin) that in the opinion of the investigator precludes participation
13. Previous randomisation in the BREATHER Plus trial
14. Known majora resistance to non-nucleoside reverse transcriptase inhibitors or integrase inhibitors

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 -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)	No
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 November 2022 to 31 March 2026