



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

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**Affiliation** UZCRC

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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.

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**Medicine Name \*** Dolutegravir with Tenofovir and Lamivudine or Emtricitabine

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**Quantity of medicine required \*** 1 500

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**7.0 PRINCIPAL INCLUSION CRITERIA \***

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1. HIV-1-infected
  2. Aged 12 to 19 years
  3. Aware of HIV status
  4. On ART for  $\geq 1$  year, with no previous regimen change for treatment failure
  5. On ART consisting of DTG, tenofovir and lamivudine/emtricitabine for  $\geq 1$  month prior to screening
  6. Virologically suppressed with all HIV-1 RNA viral loads  $< 50$ copies/mL in the last 12 months up to and including screening. Additionally, there must be one result  $< 50$ copies/mL 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
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**7.1 PRINCIPAL EXCLUSION CRITERIA \***

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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
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**7.2 PRIMARY END POINTS \***

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

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**9.0 DESIGN OF THE TRIAL**

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**Type of trial \*** Opened

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*If controlled*

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**Randomised** Yes

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**Single Blind** No

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**Double Blind** No

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**Parallel group** No

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**Cross over** No

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**Other** No

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**If yes to other, specify**

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**If controlled, specify the comparator**

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**Other medicinal product(s)** Yes

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**Placebo** No

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**Other** No

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**If yes to other, specify**

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**Other** No

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

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