

Antiretroviral research for Watoto

Submission date 19/04/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/06/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/07/2021	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=6

Contact information

Type(s)

Scientific

Contact name

Prof Diana Gibb

Contact details

Clinical Trials Unit, Medical Research Council
222 Euston Road
London
United Kingdom
NW1 2DA
+44 (0)20 7670 4709
d.gibb@ctu.mrc.ac.uk

Additional identifiers

Protocol serial number

G0300400

Study information

Scientific Title

Antiretroviral research for Watoto

Acronym

ARROW

Study objectives

The key objectives are to determine:

1. Will clinically driven monitoring (CDM) have a similar outcome in terms of disease progression or death as routine laboratory and clinical monitoring (LCM) for toxicity (haematology /biochemistry) and efficacy (CD4)?
2. Will induction with four drugs (2 antiretroviral therapy [ART] classes) followed by maintenance with three drugs after 36 weeks be more effective than a continuous non-nucleoside reverse transcriptase inhibitors (NNRTI)-based triple drug regimen in terms of CD4 and clinical outcome?

In addition there will be a sub-study to evaluate a visual analogue scale for assessing 28-day adherence to ART, by comparing with 3-day recall, pill and bottle counts (including unannounced checks at home). This will be performed on a subset of children enrolled in the trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. University College London (UCL) (UK), 25/05/2006, ref: 0701/001
2. Ugandan National Council for Science & Technology (UNCST) (Uganda), 16/02/2006
3. JCRC IRB/REC & Uganda Virus Institute Science and Ethics Committee (Uganda), 14/07/2006
4. Baylor College of Medicine (Uganda), approved on 12 October 2006 (Uganda), 12/10/2006, ref: H-19616
5. Medical Research Council of Zimbabwe (MRCZ) (Zimbabwe), 05/04/2007, ref: MRC/A/1321
6. Medicines Control Authority of Zimbabwe (MCAZ) (Zimbabwe), 04/05/2007, ref: B/279/5/52 /2007

Study design

Randomised trial of monitoring practice and induction maintenance drug regimens

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Human immunodeficiency virus

Interventions

First randomisation is to CDM or LCM (1200 children). Second randomisation is to either continuous or induction-maintenance ART strategies for first-line therapy. Children will be randomised immediately after their first randomisation to CDM or LCM.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Monitoring practice (n = 1200):

1.1. Efficacy: progression to a new WHO stage 4 or death

1.2. Safety: any adverse events of grade 3 or 4, which are not HIV-related only

2. ART strategies for first-line therapy (n=1200):

2.1. Efficacy: progression to a new WHO stage 4 or death and change in CD4 percentage at 72 and 144 weeks

2.2. Safety: any adverse events of grade 3 or 4, which are not HIV-related only

Key secondary outcome(s)

No secondary outcome measures

Completion date

14/03/2012

Eligibility

Key inclusion criteria

1. Children should have an adult carer in the household who is either:

1.1. Participating in the DART trial (ISRCTN13968779) or

1.2. Being treated with ART or

1.3. HIV positive but not yet needing treatment but with access to a treatment program when ART is required or

1.4. HIV negative

2. Parents or guardians, and children where appropriate according to age and knowledge of HIV status, must be willing and able to give informed consent for randomisation to clinically driven monitoring (CDM) or laboratory and clinical monitoring (LCM) and to first-line ART strategy

3. Participants must have a confirmed and documented diagnosis of HIV-1 infection

4. At entry participants should be aged:

4.1. 6 Months to 17 years among children and adolescents from DART households

4.2. 6 Months to 12 years among children in non-DART households

5. Participants must be ART naive (except for exposure to perinatal ART for the prevention of mother-to-child HIV transmission)

6. Participants must meet the criteria for requiring ART according to World Health Organization (WHO) stage and CD4 count or CD4 cell percent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 months

Upper age limit

17 years

Sex

All

Key exclusion criteria

1. Cannot, or unlikely to attend regularly
2. Likelihood of poor adherence
3. Presence of acute infection
4. In receipt of medication contraindicated by ART or on chemotherapy for malignancy
5. Laboratory abnormalities, which are a contraindication for the patient to start ART
6. Pregnant or breastfeeding

Date of first enrolment

02/10/2006

Date of final enrolment

14/03/2012

Locations**Countries of recruitment**

United Kingdom

England

Uganda

Zimbabwe

Study participating centre

Clinical Trials Unit, Medical Research Council

London

United Kingdom

NW1 2DA

Sponsor information**Organisation**

Medical Research Council (UK)

ROR

<https://ror.org/03x94j517>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK) (ref: G0300400)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

Department for International Development

Alternative Name(s)

Department for International Development, UK, DFID

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

Results article		20/04/2013		Yes	No
Results article	results	02/01/2014		Yes	No
Results article	results	17/07/2016		Yes	No
Results article	Sub study results		19/07/2021	Yes	No
Other publications	observational analyses	14/11/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes