

# Antiretroviral research for Watoto

<b>Submission date</b> 19/04/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/06/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/07/2021	<b>Condition category</b> 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](http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=6)

## Study website

<http://www.arrowtrial.org>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

Patient information can be found at: <http://www.arrowtrial.org/faqs.asp>

## **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 measure**

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

## **Secondary outcome measures**

No secondary outcome measures

## **Overall study start date**

02/10/2006

## **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

**Age group**

Child

**Lower age limit**

6 Months

**Upper age limit**

17 Years

**Sex**

Both

**Target number of participants**

1,200

**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**

England

Uganda

United Kingdom

Zimbabwe

**Study participating centre**  
Clinical Trials Unit, Medical Research Council  
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## Sponsor information

### Organisation

Medical Research Council (UK)

### Sponsor details

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### Sponsor type

Research council

### 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, 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

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****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?
<a href="#">Results article</a>	results	20/04/2013		Yes	No
<a href="#">Results article</a>	results	02/01/2014		Yes	No
<a href="#">Results article</a>	results	17/07/2016		Yes	No
<a href="#">Other publications</a>	observational analyses	14/11/2017		Yes	No
<a href="#">Results article</a>	Sub study results		19/07/2021	Yes	No