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Antiretroviral research for Watoto

Submission date	Recruitment status	[X] Prospectively registered
19/04/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/06/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/07/2021	Infections and Infestations	

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=6

Contact information

Type(s)
Scientific

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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
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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, 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 article	results	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