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Second-line Anti-Retroviral therapy in Africa: a randomised trial to evaluate the feasibility of maintenance monotherapy with ritonavir-boosted lopinavir (Aluvia® tablets) following initiation with 24 weeks of combination therapy in second-line anti-retroviral therapy in Africa

Submission date
02/04/2007

Recruitment status
No longer recruiting

Registration date
31/05/2007

Overall study status
Completed

Last Edited
18/12/2017

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Charles Gilks

Contact details
Faculty of Medicine
Imperial College
Norfolk Place
London
United Kingdom
W2 1PG
-
dart@ctu.mrc.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Second-line Anti-Retroviral therapy in Africa: a randomised trial to evaluate the feasibility of maintenance monotherapy with ritonavir-boosted lopinavir (Aluvia® tablets) following initiation with 24 weeks of combination therapy in second-line anti-retroviral therapy in Africa

Acronym
SARA

Study objectives
The use of ritonavir-boosted lopinavir (as Aluvia® tablets) monotherapy is an important simplification approach for second-line antiretroviral therapy in resource-limited settings.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Medicines Control Authority of Zimbabwe (MCAZ). Date of approval: 06/06/2007 (ref: B279/5/67/2007)
2. Medical Research Council of Zimbabwe (MRCZ) Date of approval: 03/03/2007 (ref: MRCZ/A/1378)
3. Ugandan National Council for Science and Technology (UNCST) Date of approval: 20/06/2007 (ref: MV 710)
4. Ugandan Virus Research Institute (UVRI SEC) Date of approval: 20/04/2007 (ref: GC/127/04/07)

Study design
Three-centre open-label randomised pilot trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
HIV/AIDS

Interventions
Comparison of two strategies for second-line antiretroviral therapy after 24 weeks of combination Aluvia® (or Kaletra®)-containing antiretroviral therapy:

Arm 1: Continued combination Aluvia-containing antiretroviral therapy
Arm 2: Maintenance with Aluvia monotherapy

The dose of Aluvia is 2 tablets twice a day (each tablet is 200 mg of lopinavir with 50 mg of ritonavir) for both arms. All drugs are taken orally.

Each patient will be randomized to one of the two arms on enrolment and start receiving the corresponding therapy until the end of the trial (September 2009). The randomization will be carried out in a 1:1 ratio.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lopinavir and ritonavir (Aluvia®/Kaletra®)

Primary outcome measure
1. Change in CD4 count at 24 weeks after randomisation (efficacy)
2. Any Serious Adverse Event (SAE), which is not HIV related only (safety)

Secondary outcome measures
1. Progression to a new or recurrent WHO stage 4 HIV event or death
2. Progression to a new or recurrent WHO stage 3 or 4 HIV event or death
3. Change in CD4 count from SARA randomisation to 48, 72 and 96 weeks
4. Any grade 3 or 4 adverse events
5. HIV RNA viral load (performed retrospectively) at 12, 24, 36, 48, 72 and 96 weeks
6. Adherence as measured by questionnaire and pill counts
7. Health economic outcomes

Overall study start date
25/07/2007

Completion date
30/09/2009

Eligibility

Key inclusion criteria
1. Enrolled in the DART trial (ISRCTN13968779 at http://www.controlled-trials.com/ISRCTN13968779)

2. Failed first-line antiretroviral therapy (clinically/immunologically) and having completed 24 weeks of second-line combination antiretroviral therapy including ritonavir-boosted lopinavir (as either Aluvia® heat-stable tablets or Kaletra® capsules)
3. Documented informed consent
4. Life expectancy of at least 3 months

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
240

Key exclusion criteria
Pregnant or breast-feeding

Date of first enrolment
25/07/2007

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
England

Uganda

United Kingdom

Zimbabwe

Study participating centre
Faculty of Medicine
London
United Kingdom
W2 1PG

Sponsor information

Organisation
Medical Research Council Clinical Trials Unit (UK)

Sponsor details
222 Euston Road
London
United Kingdom
NW1 2DA
-
dart@ctu.mrc.ac.uk

Sponsor type
Government

Website
http://www.ctu.mrc.ac.uk/

ROR
https://ror.org/001mm6w73

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (UK)

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

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?
Results article	results	01/01/2012		Yes	No