

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 31/05/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/12/2017	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

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Sponsor information

Organisation

Medical Research Council Clinical Trials Unit (UK)

Sponsor details

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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