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Comparison of facility and home-based antiretroviral therapy delivery systems in Uganda

Submission date	Recruitment status	[_] Prospectively registered
06/08/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/11/2009	Infections and Infestations	

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
4371

Study information

Scientific Title
Comparison of facility and home-based antiretroviral therapy delivery systems in Uganda: a randomised controlled trial

Study objectives
That home-based human immunodeficiency virus (HIV) care is approximately equivalent in effectiveness to facility-based HIV care.

As of 14/04/2009 this record was updated; all updates can be found under the relevant field. At this time, the anticipated end date was also amended; the initial anticipated end date was 15/02/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 14/04/2009:
1. London School of Hygiene and Tropical Medicine Ethics Committee approved on the 25th November 2004 (ref: 2058)
2. Uganda Virus Research Institute Science and Ethics Committee approved on the 20th August 2004 (ref: "A randomised trial of home or facility-based AIDS care")
3. US Centers for Disease Control and Prevention approved on the 18th January 2005 (ref: 4371)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS)

Interventions
A comparison of two different ways of providing ART in an African setting - home-based versus facility-based HIV care

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Time to detectable viral load

Secondary outcome measures
1. Adherence
2. Cost effectiveness
3. Treatment failure

Overall study start date
15/02/2005

Completion date
31/01/2009

Eligibility

Key inclusion criteria
All HIV-infected adults (aged 18 years or more) who are started on antiretroviral therapy (ART) by a service provider (The acquired immunodeficiency syndrome [AIDS] Support Organisation) and who plan to remain in the study area for 12 months.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1000

Key exclusion criteria
1. Already on ART and transferred from another centre
2. Live on islands and are difficult to follow-up

Date of first enrolment
15/02/2005

Date of final enrolment
31/01/2009

Locations

Countries of recruitment
England

Uganda

United Kingdom

Study participating centre
London School of Hygiene and Tropical Medicine (LSHTM)
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
Medical Research Council Unit on AIDS (Uganda)

Sponsor details
c/o Uganda Virus Research Institute
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Sponsor type
Research council

Funder(s)

Funder type
Research council

Funder Name
Centers for Disease Control (CDC) (USA) - Co-operative Agreement (ref: IU01-PS000065-01)

Funder Name
Medical Research Council (MRC) (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?
Protocol article	protocol	01/11/2007		Yes	No
Results article	results	19/12/2009		Yes	No