

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

Submission date
06/08/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date
26/09/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
30/11/2009

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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)

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Time to detectable viral load

Key secondary outcome(s)

1. Adherence
2. Cost effectiveness
3. Treatment failure

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Uganda

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)

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, Medical Research Committee and Advisory Council, MRC

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	19/12/2009		Yes	No
Protocol article	protocol	01/11/2007		Yes	No