

Counselling and entry into HIV care

Submission date 01/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 13/07/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/06/2015	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

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MUSPH 06012009

Study information

Scientific Title

Assessing the effect of extended counselling on uptake and adherence to pre- antiretroviral care: A longitudinal, randomised controlled trial

Acronym

pre-ARV

Study objectives

Extended counselling is associated with increased uptake and adherence to pre-antiretroviral therapy (ART)

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Makerere University School of Public Health Higher Degrees Research and Ethics Committee, 06/01/2009
2. Uganda National Council for Science and Technology

Study design

Longitudinal double-blind multicentre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Please contact Dr Muhamadi Lubega [dlmuhamadi@yahoo.co.uk] to request a patient information sheet

Health condition(s) or problem(s) studied

Pre-ARV care adherence

Interventions

Newly screened HIV positive persons will be followed and monitored for uptake and adherence to the pre-ART care for a period of 5 months depending on the frequency of enrolment of eligible subjects. The HIV positive persons from three centres will be classified into two arms.

1. Control arm: HIV positive persons will receive the current format and text of counselling
2. Intervention arm: HIV positive persons will receive a specially packaged continuum of extended counselling

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Proportion of HIV positive persons with extended counselling who adhere to pre-ART care

Secondary outcome measures

Proportion of HIV positive persons not lost to follow up during subsequent HIV care

Overall study start date

02/12/2009

Completion date

02/06/2010

Eligibility

Key inclusion criteria

Adult patients (>18 years) who test HIV positive at the ART centres at the start of the study (November 2009)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

400

Key exclusion criteria

1. Patients undergoing Prevention of Mother-To-Child Transmission (PMTCT) therapy
2. Patients who are not of sound mental status
3. Those who are expected to leave the district during the period of follow-up

Date of first enrolment

02/12/2009

Date of final enrolment

02/06/2010

Locations

Countries of recruitment

Uganda

Study participating centre

Makerere University

Kampala

Uganda

256

Sponsor information

Organisation

Swedish International Development Authority - Department for Research Cooperation (SIDA /SAREC) (Sweden)

Sponsor details

Karolinska institutet

Stockholm

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Sponsor type

Government

Website

<http://www.sida.se>

ROR

<https://ror.org/01fn7me06>

Funder(s)

Funder type

Government

Funder Name

Swedish International Development Authority - Department for Research Cooperation (SIDA /SAREC) (Sweden)

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	01/05/2010		Yes	No
Results article	results	27/07/2011		Yes	No
Results article	results	01/10/2015		Yes	No