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Home care and routine: cryptococcal meningitis screening among patients starting antiretroviral therapy with advanced disease

Submission date
10/10/2011

Recruitment status
No longer recruiting

Registration date
09/11/2011

Overall study status
Completed

Last Edited
19/07/2016

Condition category
Infections and Infestations

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
HIV is a virus that attacks the immune system, weakening its ability to fight infections and disease. It is treated with antiretroviral therapy – drugs that stop the virus replicating in the body, allowing the immune system to repair itself and preventing further damage. Mortality (death rate) is high among people in Africa with HIV who are starting antiretroviral therapy, particularly in those with advanced disease. The aim of this study is to assess the effect of a short period of community support to supplement clinic-based services, combined with testing for cryptococcal meningitis (a fungal infection of the tissues covering the brain and spinal cord).

Who can participate?
HIV-infected adults with a CD4 count of less than 200 cells per microlitre

What does the study involve?
Participants are randomly allocated to either the intervention or the control group. The intervention group receive antiretroviral therapy in a short time frame (following first presentation with HIV), home-based monitoring and adherence support (for about 6 weeks), testing for cryptococcal meningitis (and treatment if needed). All patients (both groups) are tested for tuberculosis (a bacterial infection of the lungs). An additional test for tuberculosis is carried out about 4 weeks after the start of antiretroviral therapy among patients in the intervention group. The control group receive standard care. Both groups are followed up for 12 months after the start of antiretroviral therapy.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Dar es Salaam in Tanzania and Lusaka in Zambia

When is the study starting and how long is it expected to run for?
February 2012 to December 2014

Who is funding the study?
European and Developing Countries Clinical Trials Partnership (Netherlands)

Who is the main contact?
Dr Saidi Egwaga

Contact information

Type(s)
Scientific

Contact name
Dr Saidi Egwaga

Contact details
Ministry of Health and Social Welfare
PO Box 9083
Dar es Salaam
Tanzania
N/A

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Reduction of Early Mortality among HIV-infected Subjects sTarting AntiRetroviral Therapy (REMSTART) in Zambia and Tanzania with CD4 count <200 cells per microlitre: a randomised trial involving home support and routine screening for cryptococcal meningitis

Acronym
REMSTART

Study objectives
Current hypothesis as of 09/07/2013
The intervention will reduce the high early mortality among HIV-infected patients presenting with CD4 count <200 cells per microlitre and will be cost effective in achieving this.

Previous hypothesis
The intervention will reduce the high early mortality among HIV-infected patients presenting with CD4 count <100 cells per microlitre and will be cost effective in achieving this.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. National Institute of Medical Research Ethics Committee, Tanzania, 10/08/2011
2. ERES Converge Local Ethics Committee, Zambia, 29/08/2011
3. London School of Hygiene and Tropical Medicine ethics committee, 17/11/2011

Study design
Two-arm individually randomised open-label trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Human immunodeficiency virus (HIV)

Interventions
The intervention is a complex health care delivery strategy. It comprises initiation of antiretroviral therapy in a short time frame (following first presentation with HIV), home-based monitoring and adherence support (for about 6 weeks), screening of cryptococcal meningitis using a point of care antigen test (and treatment as indicated). All patients (both arms) will be tested for tuberculosis (TB) using GeneXpert as well as classical methods (symptom history using standard questionnaire followed by smear and culture if indicated). An additional screening for tuberculosis will be done about 4 weeks after initiation of antiretroviral therapy among patients in the intervention arm. The trial will be integrated into normal health care delivery with study patients managed according to national guidelines. Services for hypertension and diabetes will be strengthened for all patients and a buffer supply of drugs will be made available to ensure continued drug supply.

The control arm is the standard of care. We will ensure that care is functional to reasonably good standards. Thus, for example, we will monitor availability of clinical staff (and arrange clinic support if necessary), ensure essential drugs supplies and antiretrovirals are available (we will purchase buffer supplies for the health service), ensure generally procedures are in line with guidelines and provide feedback of observations to the health service. This will result in a

standard of care that is better than normal health service delivery and will narrow the size of our effects. However, it is important that we compare our intervention with functional care to ensure that the results can be generalised widely.

Intervention Type
Mixed

Primary outcome measure
All-cause mortality up to 12 months after enrolment

Secondary outcome measures
1. Costs of the two strategies to the health service
2. Patient retention
3. Rate of hospital admission
4. Frequency of outpatient attendances
5. Detection of TB among patients on antiretroviral therapy (ART) and their household members
6. Detection of cryptococcal meningitis among patients with ART
7. Uptake of HIV voluntary counselling and testing and of TB screening among household members
8. Adherence to ART

Overall study start date
01/02/2012

Completion date
31/12/2014

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/07/2013:
1. CD4 < 200 cells /µl
2. Adult: ≥ 18 years
3. Antiretroviral naïve (as reported by the patient)
4. Planning to remain in the study area for about six months (as reported by the patient)

Previous inclusion criteria:
1. CD4 < 100 cells /µl
2. Adult: ≥ 18 years
3. Antiretroviral naïve (as reported by the patient)
4. Planning to remain in the study area for about six months (as reported by the patient)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2500 subjects (1250 in each arm)

Key exclusion criteria
1. Requiring immediate in-patient care/admission
2. Living outside the catchment population of the hospital

Date of first enrolment
01/02/2012

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Tanzania

Zambia

Study participating centre
Ministry of Health and Social Welfare
Dar es Salaam
Tanzania
N/A

Sponsor information

Organisation
London School of Hygiene and Tropical Medicine (UK)

Sponsor details
c/o Professor Shabbar Jaffar
Keppel Street
London
England
United Kingdom
WC1E 7HT

Sponsor type
University/education

Website
http://www.lshtm.ac.uk/

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Research organisation

Funder Name
European and Developing Countries Clinical Trials Partnership

Alternative Name(s)
Le partenariat Europe-Pays en développement pour les essais cliniques, A Parceria entre a Europa e os Países em Desenvolvimento para a Realização de Ensaios Clínicos, The European & Developing Countries Clinical Trials Partnership, European and Developing Countries Clinical Trials, EDCTP

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Netherlands

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	30/05/2015		Yes	No