

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

<b>Submission date</b> 10/10/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/11/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/07/2016	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English Summary

### 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 hypothesis**  
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

## **Condition**

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

## **Overall study end date**

31/12/2014

# **Eligibility**

## **Participant inclusion criteria**

Current inclusion criteria as of 05/07/2013:

1. CD4 < 200 cells / $\mu$ l
2. Adult:  $\geq$  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 / $\mu$ l
2. Adult:  $\geq$  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)

**Participant exclusion criteria**

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

**Recruitment start date**

01/02/2012

**Recruitment end date**

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

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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 Ensaio Clínicos, European and Developing Countries Clinical Trials, The European & Developing Countries Clinical Trials Partnership, 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?
<a href="#">Results article</a>	results	30/05/2015		Yes	No

