# A cluster randomised trial of two intensified tuberculosis case-finding strategies in an urban community severely affected by human immunodeficiency virus

<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered	
	☐ Protocol	
Overall study status	Statistical analysis plan	
Completed	[X] Results	
Condition category	Individual participant data	
	No longer recruiting  Overall study status  Completed	

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

# Secondary identifying numbers

074644; LSHTM ITCR BA79

# Study information

#### Scientific Title

A cluster randomised trial of two intensified tuberculosis case-finding strategies in an urban community severely affected by human immunodeficiency virus

#### Acronym

**DETECTB** 

## **Study objectives**

- 1. To compare the cumulative yield and residual burden of two potentially sustainable intensified TB case-finding methods applied for 3 years in a high HIV setting
- 2. To investigate HIV-specific point prevalence and incidence of active TB disease in an urban community before and after the intervention period (as of 13/02/2007 this hypothesis was changed to 'To investigate the change in point prevalence of culture-positive TB disease in an urban community before and after the intervention period')

On 13/02/2007 the overall trial end date was changed to 01/12/2008.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Not provided at time of registration

# Study design

Randomised controlled trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Not specified

# Study type(s)

Treatment

#### Participant information sheet

# Health condition(s) or problem(s) studied

**Tuberculosis** 

#### **Interventions**

Cluster-randomised trial of high density neighbourhoods in Zimbabwe

Randomisation unit: each neighbourhood site

Number of sites: 46

Each neighbourhood is randomised to receive either mobile clinic or door-to-door enquiry.

Open cohort of all adults living in households within study neighbourhoods (~120,000 in total). Stratified randomisation according to pre-intervention TB case-notification rates.

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

Cumulative yield of TB cases detected through six rounds of periodic (six-monthly) case-finding intervention delivered through either:

- 1. House-to-house enquiry for chronic coughers
- 2. Mobile diagnostic clinic visits

#### Secondary outcome measures

HIV-specific point prevalence and incidence of active TB disease before and immediately after the intervention (for whole study area with both arms combined) - as of 13/02/2007 this secondary outcome measure was changed to: 'Point prevalence of culture-positive TB disease before and immediately after the intervention (for whole study area with both arms combined)'.

# Overall study start date

01/02/2006

# Completion date

01/12/2008

# **Eligibility**

#### Key inclusion criteria

Site:

- 1. Study neighbourhoods based on Census Evaluation Units (CEUs) in residential suburbs of South-West and Western Harare
- 2. Three to four CEUs combined to provide:
- a. 2000-3000 adults registered for 2002 Census
- b. No flats or Halls of Residence
- c. At least 500 km distance between study neighbourhoods

All eligible neighbourhoods included

## Participant type(s)

Patient

#### Age group

Adult

#### Sex

Both

#### Target number of participants

120,000 - 110,000 as of 07/08/2006 (end of recruitment)

# Key exclusion criteria

Individual:

- 1. Declined consent to participate
- 2. Aged below 16 years

#### Date of first enrolment

01/02/2006

#### Date of final enrolment

07/08/2006

# Locations

#### Countries of recruitment

England

**United Kingdom** 

Zimbabwe

# Study participating centre London School of Hygiene and Tropical Medicine

London United Kingdom WC1E 7HT

# Sponsor information

#### Organisation

London School of Hygiene and Tropical Medicine (UK)

### Sponsor details

Keppel Street London England United Kingdom WC1E 7HT +44 (0)20 7636 8636 Penny.Ireland@lshtm.ac.uk

#### Sponsor type

University/education

#### Website

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

#### **ROR**

https://ror.org/00a0jsq62

# Funder(s)

# Funder type

Charity

#### **Funder Name**

Wellcome Trust (UK) (grant ref: 074644)

# Alternative Name(s)

#### **Funding Body Type**

Private sector organisation

# **Funding Body Subtype**

International organizations

#### 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?
Results article	results	09/10/2010		Yes	No