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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered	
14/10/2005		☐ Protocol	
Registration date 14/10/2005	Overall study status Completed	Statistical analysis plan	
		[X] Results	
Last Edited 19/06/2015	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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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