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# The Zambia, South Africa, Tuberculosis and Acquired Immune Deficiency Syndrome-reduction Trial

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 07/04/2006 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 05/05/2006 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 16/12/2021 | Infections and Infestations | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Peter Godfrey-Faussett

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
19790.03

# Study information

## Scientific Title
The Zambia, South Africa, Tuberculosis and Acquired Immune Deficiency Syndrome-reduction Trial

## Acronym
ZAMSTAR

## Study objectives
Two new approaches to improving case detection of tuberculosis in communities with a high burden of tuberculosis and human immunodeficiency virus (HIV) are able to reduce the prevalence of tuberculosis (TB) at a community level over a three year period

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved by the London School of Hygiene and Tropical Medicine on 14/03/05, reference number: 3008; approved by the University of Zambia on 15/12/04 and also approved by the University of Stellenbosch on 18/01/05 reference number: N04/10/173

## Study design
Community randomised, factorial design

## 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
The two interventions are:
1. Improved case finding: by allowing individuals direct access to diagnostic services and empowering communities to seek care, we will bypass the health system barriers and greatly reduce the number of people who are spreading infection
2. Integrated TB/HIV care delivered through the household: by harnessing the capacity of

households and the community we will reduce the burden on the health system, increase the coverage and efficiency of preventive and curative tuberculosis services and break down the barriers of stigma and denial

The two interventions described are divided equally among the 24 randomised communities: six will receive both, another six will receive improved case finding only, another six will receive integrated TB/HIV care delivered through the household and another six will receive neither. All communities benefit from support to the general health service to improve routine TB/HIV activities that are not part of either interventions.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
The primary outcome will be the prevalence of culture-positive tuberculosis among a randomly selected population of adults in each arm of the trial, measured after 3 years of the interventions

### Secondary outcome measures
Secondary outcomes measured at the community level include:
1. Cumulative incidence of tuberculosis infection in school children
2. Indicators of tuberculosis and HIV programme performance

At the household level, they include:
1. Cumulative incidence of tuberculosis
2. Changes in HIV incidence and stigma

### Overall study start date
01/07/2006

### Completion date
01/07/2010

## Eligibility

### Key inclusion criteria
Population served by tuberculosis diagnostic centre in each of 24 communities

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants

1,500,000

**Key exclusion criteria**
Individuals who do not consent to trial procedures

**Date of first enrolment**
01/07/2006

**Date of final enrolment**
01/07/2010

# Locations

**Countries of recruitment**
England

South Africa

United Kingdom

Zambia

**Study participating centre**
**London School of Hygiene and Tropical Medicine (LSHTM)**
London
United Kingdom
WC1E 7HT

# Sponsor information

**Organisation**
Consortium to Respond Effectively to the AIDS-Tuberculosis Epidemic (CREATE) (USA)

**Sponsor details**
Johns Hopkins Center for Tuberculosis Research
1820 Lancaster Street/Suite 300
Baltimore
Maryland
United States of America
21231

**Sponsor type**
Charity

**Website**

http://www.tbhiv-create.org

**ROR**
https://ror.org/00za53h95

# Funder(s)

**Funder type**
Charity

**Funder Name**
Bill and Melinda Gates Foundation - CREATE (Consortium to Respond Effectively to the AIDS-Tuberculosis Epidemic)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**
Not provided at time of registration

**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 | 05/10/2013 | | Yes | No |
| Other publications | secondary analysis | 14/12/2021 | 16/12/2021 | Yes | No |