

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

Submission date 07/04/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 05/05/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/12/2021	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

01/07/2010

Eligibility

Key inclusion criteria

Population served by tuberculosis diagnostic centre in each of 24 communities

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

South Africa

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)

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

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