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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

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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