ISRCTN63327174 https://doi.org/10.1186/ISRCTN63327174

Effect of community-wide isoniazid preventive therapy on tuberculosis among South African gold miners (Thibela TB)

Submission date	Recruitment status	[X] Prospectively registered
25/04/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/06/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/01/2014	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.tbhiv-create.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

#19790.02

Study information

Scientific Title

Study objectives
Community-wide tuberculosis (TB) case-finding, treatment of active TB and TB preventive therapy are effective ways of rapidly reducing the burden of TB infection and disease, and can improve TB control in high human immunodeficiency virus (HIV) prevalence areas.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of KwaZulu Natal ref AHR-1-200, approved 31/03/2006; London School of Hygiene and Tropical Medicine reference number: 3064, approved 02/12/2005

Study design
Cluster, randomized, non-blinded controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

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

Interventions
Community-wide isoniazid preventive therapy. Individuals in the control clusters will receive a normal standard of TB care as per standards set down by the local TB control programme (an expanded directly observed treatments [DOTS] package, including TB preventive therapy targeted to high risk individuals, according to local policy).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Isoniazid

Primary outcome measure
Overall TB incidence in the final 12 months of follow up

Secondary outcome measures
1. TB case notification rates during months 0 to 24 after enrolment
2. Trends in TB case notification rates
3. TB prevalence at the end of the follow-up period (as measured by sputum culture positivity)
4. All-cause mortality during months 0-24 of the follow-up period
5. Case notification rate of isoniazid-resistant TB
6. Safety of community-wide isoniazid preventive therapy (IPT)

Overall study start date
19/06/2006

Completion date
19/06/2010

Eligibility

Key inclusion criteria
All employees working within the study clusters are eligible for participation in the study as a whole, there are no specific exclusion criteria. Employees at clusters allocated to the intervention will be eligible for isoniazid preventive therapy.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Around 70,000 overall

Key exclusion criteria
1. Active TB (confirmed or suspected)
2. Weight less than 40 kg
3. Known or suspected hypersensitivity to isoniazid (INH)
4. Self-reported chronic liver disease or symptoms suggesting active hepatitis (jaundice, nausea, vomiting, right upper quadrant pain, dark urine, pale stools)
5. Alcohol use exceeding 28 units per week (men) or 21 units per week (women)
6. History of convulsions
7. History of psychosis
8. Peripheral neuropathy grade 2 or greater, as defined by the aquired immune deficiency syndrome (AIDS) clinical trials group classification of adverse events

9. Pregnancy and up to three months post-partum, or breastfeeding
10. Women of child bearing potential who decline to use contraception
11. Receipt of another investigational drug or product within the previous 30 days
12. Concomitant medication with phenytoin, carbamazepine, warfarin, theophylline, disulfiram, selective serotonin re-uptake inhibitor antidepressants (e.g. citalopram, fluoxetine, paroxetine, sertraline), oral ketoconazole or itraconazole

Date of first enrolment
19/06/2006

Date of final enrolment
19/06/2010

Locations

Countries of recruitment
South Africa

Study participating centre
PO Box 61587
Johannesburg
South Africa
Gauteng 2107

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, MD
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 - Consortium to Respond Effectively to the AIDS-Tuberculosis Epidemic (CREATE), reference number: 19790.02

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	23/01/2014		Yes	No