

Economic incentives for improving cure and treatment completion rates in patients with tuberculosis (TB) in South Africa: a study of feasibility and effectiveness

Submission date 17/04/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/04/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/06/2014	Condition category Infections and Infestations	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

083619

Study information

Scientific Title

Economic incentives for improving clinical outcomes in patients with tuberculosis (TB) in South Africa: a pragmatic unblinded two-armed cluster randomised study of feasibility and effectiveness

Study objectives

Tuberculosis (TB) affects poor people disproportionately, and the costs of accessing treatment may be a profound financial stress for the household. Assisting TB patients financially may help them to adhere to treatment, and so improve clinical outcomes.

As of 05/01/2010 this record has been updated to include a change to the protocol in order to accept child participants and amendments to the start and end dates of this trial. All details can be found under the relevant section with the update date of 05/01/2010. The initial trial dates were as follows at the time of registration:

Initial anticipated start date: 01/06/2009

Initial anticipated end date: 30/04/2010

Ethics approval required

Old ethics approval format

Ethics approval(s)

Committee for Human Research at the University of Stellenbosch, South Africa, approved on the 6th February 2008 (and has subsequently been granted a year's extension on 4th March 2009) (ref: N07/10/245). Amendments from 05/01/2010 were granted approval by the Committee for Human Research at the University of Stellenbosch.

Study design

Multicentre pragmatic unblinded two-armed cluster randomised trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Drug sensitive tuberculosis

Interventions

The intervention will be a voucher, valued at R120.00 (approximately US \$15.00), given every month for the duration of TB treatment or a maximum of 6 months for drug sensitive cases, and 8 months for re-treatment or drug resistant cases. Vouchers will be administered by clinic nurses treating patients with TB. This voucher will be redeemable at a designated shop, for any goods (although the patient will be encouraged to purchase healthy foodstuffs). All TB patients within intervention clinics will receive the voucher. Patients at control clinics will receive routine TB treatment. Patients from intervention and control clinics will be followed up to the end of their TB treatment (6 months for drug sensitive cases, and 8 months for re-treatment).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Cure: patient who is sputum smear-negative in the last month of treatment and on at least one previous occasion
2. Treatment completion: patient who has completed treatment but who does not meet the criteria to be classified as a cure or a failure. (World Health Organization. Global Tuberculosis Control: Surveillance, Planning, Financing. WHO Report 2004).

These measures will be obtained from the clinic-maintained TB register, in which all patient outcomes are recorded. Outcomes are recorded at the end of patient treatment (6 months for drug sensitive cases, and 8 months for re-treatment).

Secondary outcome measures

1. Treatment failure: patient who is sputum smear-positive at 5 months or later during treatment
2. Default: patient whose treatment was interrupted for two consecutive months or more. (World Health Organization. Global Tuberculosis Control: Surveillance, Planning, Financing. WHO Report 2004).

These measures will be obtained from the clinic-maintained TB register, in which all patient outcomes are recorded. Outcomes are recorded at the end of patient treatment (6 months for drug sensitive cases, and 8 months for re-treatment).

Overall study start date

01/07/2009

Completion date

31/07/2010

Eligibility

Key inclusion criteria

Current inclusion criteria as of 05/01/2010:

1. With tuberculosis (TB), including re-treatment cases
2. Both men and women, all ages

Initial inclusion criteria at time of registration:

1. Aged 18 years and older
2. With tuberculosis (TB), including re-treatment cases
3. Both men and women

Participant type(s)

Patient

Age group

Other

Lower age limit

18 Years

Sex

Both

Target number of participants

A total of 20 clinics (clusters) will be included (10 intervention and 10 controls). This amounts to approximately 1000 participants across both arms and in both districts.

Key exclusion criteria

Current exclusion criteria as of 05/01/2010:

Patients with multi-drug resistant (MDR) or extremely drug-resistant (XDR) TB will be excluded from the analysis. However, they will receive the vouchers for a maximum of 8 months of the study.

Initial exclusion criteria at time of registration:

1. Children less than 18 years
2. Patients with multi-drug resistant (MDR) or extremely drug-resistant (XDR) TB will be excluded from the analysis. However, they will receive the vouchers for a maximum of 8 months of the study.

Date of first enrolment

01/07/2009

Date of final enrolment

31/07/2010

Locations

Countries of recruitment

South Africa

Study participating centre

Health Systems Trust
Durban
South Africa
4000

Sponsor information

Organisation

Medical Research Council of South Africa (South Africa)

Sponsor details

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Sponsor type

Research council

Website

<http://www.mrc.ac.za>

ROR

<https://ror.org/05q60vz69>

Funder(s)

Funder type

Government

Funder Name

South African National Department of Health (South Africa) - via the Research Directorate

Funder Name

The Royal Netherlands Tuberculosis Association (KNCV) (Netherlands) - via the TB CAP programme

Funder Name

The Wellcome Trust (UK) (grant ref: 083619)

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	28/05/2013		Yes	No
Results article	results	19/06/2014		Yes	No