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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

Registration date
21/04/2009

Overall study status
Completed

Last Edited
30/06/2014

Condition category
Infections and Infestations

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] 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
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 intial 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 randomided trial

Primary study design
Interventional

Study type(s)
Treatment

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(s)
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).

Key secondary outcome(s))
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).

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

Healthy volunteers allowed
No

Age group
Other

Lower age limit
18 years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 05/01/2010:
Patients with multi-drug resistant (MDR) or extremely drug-resistent (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-resistent (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)

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes