ISRCTN79888843 https://doi.org/10.1186/ISRCTN79888843

RapTB - evaluation of techniques for tuberculosis diagnosis

Submission date	Recruitment status	[_] Prospectively registered
05/05/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/01/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/07/2013	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Pragmatic clinical trial and cost-effectiveness evaluation of techniques for the sensitive and resistant tuberculosis diagnosis in patients assisted at two hospitals in Rio de Janeiro - Brazil

Acronym
RapTB

Study objectives
The implantation of a new technology (BD960) for the tuberculosis (TB), multi-drug resistant (MDR)/TB investigation in hospital units, besides reducing the intra-hospital TB transmission and the cost of the hospitalised patients treatment, will also greatly reduce the morbid/lethality of TB patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Research Ethics Committee of University Hospital Clementino Fraga Filho at the Federal University of Rio de Janeiro (ref: 020/07)

Study design
Pragmatic multicentre open randomised clinical 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
Tuberculosis

Interventions
The diagnostic test used in the routine, the Löwenstein Jensen Proportion Method, will be compared to BACTEC™ MGIT™ 960 System.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Proportion of patients for whom medical procedure is changed
after 60 days (stopping or initiating anti-TB drugs).

Secondary outcome measures
Patients will be followed for 180 days after randomisation. At the end of this period
we will measure:
1. Number of participants lost to follow-up
2. Number of deaths by any cause in the patients included in the study
3. Number of adverse effects to the drugs
4. Proportion of patients with TB diagnosis sensitive or resistant to anti-TB drugs
5. Proportion of patients that undergo anti-TB treatment failure during the therapy
6. Proportion of drug resistant TB development in the patients
7. Time to sensitivity determination to drugs
8. Proportion of bacteriological conversion (bacilloscopy and culture for mycobacterium) due to the anti-TB treatment at the end of the second and sixth month of anti-TB treatment
9. Cost of the pulmonary TB diagnostic test, for each test, and for the anti-TB treatment
10. Cost of the resistant pulmonary TB diagnostic test for each test and for the anti-TB treatment
11. Cost for the patient and family nucleus in relation to the TB diagnosis
12. Cost for the public health system (SUS) in relation to the TB diagnosis
13. Proportion of necessary human resources for the accomplishment of the TB diagnostic test
14. Proportion of necessary human resources for the resistant TB diagnostic test

Overall study start date
01/08/2008

Completion date
01/09/2010

Eligibility

Key inclusion criteria
1. Individuals aged 18 years or more, either sex
2. Assisted in two university hospitals in the southeast area of Brazil
3. Under tuberculosis suspicion (TB)
4. With or without anti-TB treatment in the past

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
706 individuals

Key exclusion criteria
Individuals who refuse to participate

Date of first enrolment
01/08/2008

Date of final enrolment
01/09/2010

Locations

Countries of recruitment
Brazil

Study participating centre
INCQS - Instituto Nacional de Controle em Qualidade de Saúde
Rio de Janeiro
Brazil
21.040-900

Sponsor information

Organisation
Brazilian Tuberculosis Research Network (Rede Brasileira de Pesquisa em Tuberculose [REDE-TB]) (Brazil)

Sponsor details
Av. Carlos Chagas Filho,
791 - Cidade Universitária,
Ilha do Fundão
Rio de Janeiro
Brazil
21941-904

Sponsor type
Research organisation

Website
http://www.redetb.org

Funder(s)

Funder type
Government

Funder Name
Brazilian Ministry of Health/UNESCO (Brazil) - Pragmatic Diagnostic Trials on TB (ref: 914BRA2000 - DECIT PRODOC, Processo FUJB no. 11.125-2)

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	01/05/2013		Yes	No