RapTB - evaluation of techniques for tuberculosis diagnosis

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Gisele Huf

Contact details

INCQS - Instituto Nacional de Controle em Qualidade de Saúde Av. Brasil, 4365 - Manguinhos Rio de Janeiro Brazil 21.040-900

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 [REDETB]) (Brazil)

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

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