

RapTB - evaluation of techniques for tuberculosis diagnosis

Submission date
05/05/2009

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
07/01/2010

Overall study status
Completed

Statistical analysis plan

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
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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 [REDE-TB]) (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