

# RapTB - evaluation of techniques for tuberculosis diagnosis

<b>Submission date</b> 05/05/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 07/01/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/07/2013	<b>Condition category</b> 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

**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?
<a href="#">Results article</a>	results	01/05/2013		Yes	No