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Impact of a novel molecular tuberculosis (TB) diagnostic system in patients at high risk of TB mortality in rural South Africa

Submission date
15/06/2011

Recruitment status
No longer recruiting

Registration date
17/06/2011

Overall study status
Completed

Last Edited
25/07/2017

Condition category
Infections and Infestations

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
HIV and tuberculosis (TB) infections are the leading causes of death for young adults in South Africa. TB bacteria that have developed resistance to first-line TB drugs (multidrug-resistant TB or MDR-TB) are now causing significant numbers of deaths. Diagnosis of MDR-TB is a laborious process which can take two to three months, by which time up to half of those with MDR-TB will have died. The Xpert MTB/RIF system is a new diagnostic test which can identify TB and can also recognise whether or not there is drug resistance within two hours. Hlabisa sub-district in KwaZulu-Natal is one place where MDR-TB has become very common in association with high levels of HIV infection. This study aims to investigate the impact of the Xpert MTB/RIF system, specifically whether outcomes are different when the system is positioned at different levels of the health system.

Who can participate?
Patients aged 18 or older with suspected TB, who have a confirmed HIV infection and/or are at high risk for MDR-TB

What does the study involve?
Participants are randomly allocated to one of two strategies: Xpert MTB/RIF testing at a district hospital laboratory or Xpert MTB/RIF testing at a primary health care clinic (point-of-care). The number of TB patients starting appropriate treatment within 30 days, the time taken to start TB treatment, and the number of deaths and hospital admissions in first 60 days are all measured.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Africa Centre for Health and Population Studies (South Africa)

When is the study starting and how long is it expected to run for?
July 2011 to December 2012

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Dr Richard Lessells
rlessells@africacentre.ac.za

Contact information

Type(s)
Scientific

Contact name
Dr Richard Lessells

Contact details
Africa Centre for Health and Population Studies
PO Box 198
Mtubatuba
South Africa
3935
+27 (0)35 550 7500
rlessells@africacentre.ac.za

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Wellcome Trust grant number 090999/Z/09/Z, South African National Clinical Trials Registry DOH-27-0711-3568

Study information

Scientific Title
Impact of a novel molecular tuberculosis (TB) diagnostic system in patients at high risk of TB mortality in rural South Africa: a pragmatic cluster randomised controlled trial

Study objectives
Timely initiation of appropriate tuberculosis (TB) treatment will be improved when the diagnostic system is positioned at the primary health care clinic (point-of-care) compared to when it is positioned centrally at the district hospital laboratory.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of KwaZulu-Natal Biomedical Research Ethics Committee, ref: BF033/11
2. London School of Hygiene and Tropical Medicine Ethics Committee, ref: 5926
Approval pending as of 15/06/2011

Study design
Single-centre cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Pulmonary tuberculosis

Interventions
Comparison between two delivery strategies for the GeneXpert system and Xpert MTB/RIF test: Positioning at district hospital vs positioning at primary health care clinic

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Proportion of TB cases initiated on appropriate TB treatment within 30 days of enrolment

Secondary outcome measures
1. Time to initiation of appropriate TB treatment
2. Time to initiation of appropriate MDR-TB treatment
3. All-cause mortality at 60 days
4. Hospital admissions in first 60 days
5. Time to initiation of antiretroviral therapy (for eligible HIV-infected participants)

Overall study start date
04/07/2011

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. TB suspect (defined as cough of any duration)
2. Age 18 years or older
3. Confirmed human immunodeficiency virus (HIV) infection and/or high risk for multi-drug-resistant tuberculosis (MDR-TB)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2000

Key exclusion criteria
1. Severely unwell requiring admission to hospital
2. Previous MDR/extensively drug-resistant tuberculosis (XDR-TB) diagnosis or treatment
3. Diagnosis or suspicion of extra-pulmonary TB only
4. Unable to give informed consent

Date of first enrolment
04/07/2011

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
South Africa

Study participating centre
Africa Centre for Health and Population Studies
Mtubatuba
South Africa
3935

Sponsor information

Organisation
London School of Hygiene and Tropical Medicine (UK)

Sponsor details
Research Grants & Contracts Office
Keppel Street
London
England
United Kingdom
WC1E 7HT
+44 (0)20 7927 2626
patricia.henley@lshtm.ac.uk

Sponsor type
University/education

Website
http://www.lshtm.ac.uk

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (UK) (090999/Z/09/Z)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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?
Protocol article	protocol	12/06/2013		Yes	No
Results article	results	01/10/2017		Yes	No