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Xpert for Tuberculosis: Evaluating a New Diagnostic (XTEND)

Submission date	Recruitment status	[_] Prospectively registered
25/10/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/11/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/03/2017	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Tuberculosis (TB) is an infection that mainly affects the lungs, caused by a type of bacterium called Mycobacterium tuberculosis. The Xpert MTB/RIF is an automated diagnostic test that can identify Mycobacterium tuberculosis (MTB) DNA and resistance to the anti-tuberculosis drug rifampicin (RIF). The aim of this study is to find out whether using Xpert MTB/Rif reduces early mortality (death) in patients suspected of having TB, and its cost-effectiveness when used in a routine setting. The overall goal is to better understand how Xpert MTB/RIF should be best used when rolled out nationally in South Africa.

Who can participate?
Patients aged 18 and over suspected of having TB

What does the study involve?
Participating laboratories are randomly allocated to one of two groups. Laboratories in one group test patients' sputum (phlegm) using a routine TB test (smear) and the other group use the new Xpert MTB/RIF test. Patients who are found to have multi-drug-resistant TB are given the appropriate treatment. After a 6-month follow-up period, the outcomes of the TB patients are compared and the costs and effectiveness of the MTB/RIF test are calculated.

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

Where is the study run from?
The Aurum Institute (South Africa)

When is the study starting and how long is it expected to run for?
November 2011 to February 2014

Who is funding the study?
Bill and Melinda Gates Foundation (USA)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
XTEND - Xpert MTB/RIF - TB

Study information

Scientific Title
Xpert MTB/RIF for diagnosis of tuberculosis: evaluating impact and cost-effectiveness in the routine roll-out in South Africa

Acronym
XTEND

Study objectives
The overall goal of the project is to better understand how Xpert Mycobacterium tuberculosis/ resistance to rifampicin (MTB/RIF) should be best used under conditions of national roll-out by determining its effectiveness and cost effectiveness, and modelling these data to project the impact at population level in South Africa.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. University of the Witwatersrand, 10/10/2011, ref: M110827
2. The National South African Department of Health (SANCTR, DoH), ref: DOH-27-1011-3849
3. The London School of Hygiene and Tropical Medicine, 07/10/2011, ref: 6041
4. University of Cape Town, 20/10/2010, ref: 363/2011

Study design
Pragmatic randomised trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Tuberculosis

Interventions
The intervention is the implementation of the GeneXpert MTB/RIF Diagnostic Instrument at randomised laboratories. The intervention laboratories will receive Xpert MTB/RIF, with one Xpert MTB/RIF test replacing the two smears at diagnosis. Patients that are sputum Xpert MTB /RIF positive (rifampicin-sensitive) will have a second sputum specimen collected for smear microscopy, to enable reporting of treatment outcomes according to World Health Organisation (WHO) definitions. Patients that are sputum Xpert MTB/RIF rifampicin resistant will be initiated on treatment for Multi-drug-resistant tuberculosis (MDR-TB) pending confirmation of drug susceptibility testing (DST) on positive cultures.

The control laboratories will continue to operate the existing standard of care, as per South African National Guideline, with two smears done for all TB suspects, and culture done if smear negative and symptomatic, if high MDR-risk.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The effectiveness of Xpert MTB/RIF in reducing early mortality in TB suspects

Key secondary outcome(s))
1. The primary default rate among newly diagnosed TB cases
2. The time from enrolment to start of treatment for drug susceptible TB and appropriate treatment for drug-resistant TB
3. The incremental cost per life saved and disability-adjusted life year (DALY) averted, including reductions in transmission of drug susceptible and drug resistant TB, from a provider and client perspective

Completion date
28/02/2014

Eligibility

Key inclusion criteria
1. The laboratories are placed in four Provinces geographically separate in serving a mix of clinics that have been allocated a GX16 Machine
2. Tuberculosis (TB) suspected participants contribute towards samples evaluated in the laboratories
3. Male and female participants
4. Aged 18 and above

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. The laboratories part of other TB Xpert MTB/RIF evaluations
2. Laboratories which already have an Xpert MTB/RIF instrument
3. Laboratories which do not comply with standard of care TB diagnostics

Date of first enrolment
01/11/2011

Date of final enrolment
28/02/2014

Locations

Countries of recruitment
South Africa

Study participating centre
The Aurum Institute
Johannesburg
South Africa
2193

Sponsor information

Organisation
Bill and Melinda Gates Foundation (USA)

ROR
https://ror.org/0456r8d26

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation (USA)

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2015		Yes	No