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A multi-centric trial of front-loaded smear microscopy in the diagnosis of tuberculosis

Submission date	Recruitment status	[_] Prospectively registered
23/01/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/04/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/10/2016	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
07.35; A70394

Study information

Scientific Title
A multi-centric trial of front-loaded smear microscopy in the diagnosis of tuberculosis

Acronym

TB-TSDSS (TuBerculosis - Two Same Day Sputum Specimens)

Study objectives
1. To determine the sensitivity, specificity and predictive values of a "two samples in a single day" strategy for the diagnosis of tuberculosis (TB) and compare it to the standard strategy
2. To determine the proportion of patients who could initiate treatment (or who are referred to initiate treatment) 24, 48 or greater than or equal to 72 hours after consultation by the "two samples in a single day" and the standard strategies
3. To describe the effect of using different thresholds to define a positive smear and a smear positive case on the yield of the "two samples in a single day" and standard strategies

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. World Health Organization (WHO) Research Ethics Committee, September 2007
2. Nigeria National Ethics Committee, 23/07/2007
3. Brazil National Ethics Committee, 12/10/2007
4. Ethopia National Ethics Committee, 10/01/2008
5. Nepal National Ethics Committee, 22/07/2007
6. Yemen National Ethics Committee, 27/06/2007
6. Liverpool School of Tropical Medicine Research Ethics Committee, 07/06/2007, ref: 07.35

Primary study design
Interventional

Study design
Interventional randomised controlled two-armed study

Study type(s)
Diagnostic

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

Interventions
Scheme one: experimental arm -
Each patient attending during this week will be requested to provide:
1. One on-the-spot sputum sample at the time of the patient's first visit
2. A second on-the-spot sample taken one hour after the first one
3. An early morning sputum sample taken by the patient at home on the day following the initial visit

Scheme two: current standard -
Each patient attending during this week will be requested to provide:
1. One on-the-spot sputum sample at the time of the patient's first visit
2. An early morning sputum sample taken by the patient at home on the day following the initial visit
3. A second on-the-spot sample taken at the time the patient brings his early morning sample

There is no long term follow up of patients. Patients are managed by the National TB control programmes. It is intended that enrolment of patients will take a minimum of 10 months and may continue until the sample size is complete.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
These outcomes will be established for each diagnostic strategy and will use culture as gold standard:
1. Sensitivity, specificity, positive and negative predictive value of smear microscopy when using:
1.1. The WHO case definitions for smear-positive tuberculosis
1.2. The first two specimens collected by each strategy (spot and extra-spot versus spot and morning)
2. The number of patients referred to a TB treatment centre 24, 48 and 72 hours after their initial consultation
3. The number of patients who drop out of the diagnostic process

Key secondary outcome(s)
1. Sensitivity, specificity, positive and negative predictive value of:
1.1. A single positive smear
1.2. A single positive smear considering smears with scanty acid-fast bacilli (AFB) as positive
1.3. The smears collected as spot, extra-spot and morning or spot-morning-spot
2. Proportion of patients with positive culture identified by two smears prepared from a single specimens
3. The incremental yield of the second and third samples

Completion date
01/01/2009

Eligibility

Key inclusion criteria
1. Symptoms suggesting pulmonary TB: persistent cough (generally greater than two weeks)
2. Provision of informed consent to participation
3. Age greater than 18 years old, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Inability to provide informed consent (e.g., unfamiliarity with language of patient information /consent forms, prisoners, mentally impaired)
2. Anti-tuberculous treatment in the last month

Date of first enrolment
06/01/2008

Date of final enrolment
01/01/2009

Locations

Countries of recruitment
United Kingdom

England

Brazil

Ethiopia

Nepal

Nigeria

Yemen

Study participating centre
Liverpool School of Tropical Medicine
Liverpool
United Kingdom
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Sponsor information

Organisation
Liverpool School of Tropical Medicine (UK)

ROR

https://ror.org/03svjbs84

Funder(s)

Funder type
Research organisation

Funder Name
United Nations Children's Fund (UNICEF)/United Nations Development Programme (UNDP)/World Bank/World Health Organization (WHO) - Special Programme for Research and Training in Tropical Diseases (TDR)

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	01/07/2011		Yes	No
Results article	results	01/07/2011		Yes	No
Results article	results	24/03/2016		Yes	No