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Increasing tuberculosis case detection and reducing gender disparities through sputum submission instructions: a randomised controlled trial in Pakistan

Submission date
13/09/2005

Recruitment status
No longer recruiting

Registration date
03/11/2005

Overall study status
Completed

Last Edited
06/07/2007

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Giving women instructions on how to provide sputum samples will increase the yield of smear positive tuberculosis diagnoses in a chest clinic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet

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

Interventions
Patients in the intervention arm were referred to a designated room at the TB centre where they received guidance from a female health worker who was trained by the researcher and a senior TB control officer to provide sputum submission instructions. The female health worker was not involved in recruitment or randomisation. The following points were explained in detail to patients:
1. The importance of submitting sputum rather than saliva, and a description of visual difference between the two
2. The technique that should be used to produce a good sputum specimen (take three deep breaths, followed by a deep cough to bring up sputum from your lungs)
3. The necessity of filling at least one-quarter of the container (5 ml), shown by pointing out the required level on a demonstration container
4. The importance of providing one spot specimen and returning the next day with another specimen which has been expectorated on awakening that morning

Following instructions, which lasted between 2-3 min, patients in the intervention group were directed to the laboratory to obtain sputum submission containers.

Control group: usual procedure

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome measure was specimen smear-positivity.

Secondary outcome measures
The secondary outcome, specimen quality, was determined by visual assessment of specimens and microscopic assessment of Ziehl-Neelsen (ZN) stained smears, using a modification of the rating system of Bartlett.
Specimens with a purulent/mucoid/blood-stained visual appearance and/or containing polymorphoneutrophils (PMNs) on microscopic inspection were designated sputum.
Specimens with a clear/watery appearance containing squamous epithelial cells, but no PMNs were designated saliva.

Overall study start date
01/07/2005

Completion date
01/09/2005

Eligibility

Key inclusion criteria
New male and female tuberculosis (TB) suspects, who were referred by TB centre physicians for initial diagnostic sputum testing, were eligible to participate in the trial. According to the National Tuberculosis Control programme guidelines, the criteria for enrolment were:
1. History of a cough for >3 weeks and/or fever for 1 month
2. Blood in sputum
3. Night sweats
4. Weight loss
5. Loss of appetite

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
2600

Key exclusion criteria
1. Age over 75 or below 14 years
2. History of TB diagnosis or treatment
3. Intake of oral steroids in the 3 months leading up to presentation

Date of first enrolment
01/07/2005

Date of final enrolment
01/09/2005

Locations

Countries of recruitment
England

Pakistan

United Kingdom

Study participating centre
Keppel Street
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
London School of Hygiene and Tropical Medicine (UK)

Sponsor details
Keppel Street
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England
United Kingdom
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Sponsor type
University/education

Website

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

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
Department for International Development (DFID) (UK) - Knowledge Programme on Tuberculosis

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?
Results article	Results	09/06/2007		Yes	No