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An intervention to stop tobacco use among patients suspected of tuberculosis (TB)

Submission date	Recruitment status	[_] Prospectively registered
05/12/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/03/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/07/2013	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
An intervention to stop tobacco use among patients suspected of tuberculosis (TB): an evaluation of an integrated approach

Acronym
TATO

Study objectives
1. What is the effect of an intervention, based on the World Health Organization (WHO) 'five steps to quit' model and consisting of training of health professionals, a desk-guide, a desktop patient education tool and leaflet, on patients' point and continuous abstinence from tobacco use? [Effect evaluation]
2. To what extent do the health professionals communicate risks of tobacco use and benefits of its cessation to their patients? What are their experiences and opinions about this strategy? [Process evaluation]
3. How do patients experience the intervention for tobacco addiction? [Ethical evaluation]
4. What is the incremental cost-effectiveness ratio of the intervention for tobacco addiction compared to usual care? [Economic evaluation]

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committees of TB programme and Pakistan Medical Research Council, approval pending as of 05/12/2008.

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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 and tobacco use

Interventions
A total of 22 primary care health centres will be selected (11 each for control and intervention arms) and 50 patients recruited with suspected tuberculosis in each of these centres.

In the intervention arm, recruited patients will be given the 'five steps to quit' model. This is based on the evidence-based recommendations for treatment of tobacco addiction published by WHO in 2001. Participants will be:
1. Asked about the status of nicotine use
2. Advised about the benefits of stopping nicotine use
3. Assessed for their motivation to stop its use
4. Assisted in stop attempts through various therapeutic options
5. Provided with an information leaflet
6. Asked to arrange a follow-up

In the control arm, patients will be provided with education leaflets only.

The trial will continue for six months and a review at 1 and 6 months will take place to assess smoking status and clinical outcomes in both arms.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Point abstinence at 4 weeks: the proportion of trial participants who have completely given up all forms of nicotine use at four weeks after the completion of NRT, bupropion and/or brief counselling therapy
2. Continuous abstinence up to 6 months: proportion of trial participants who remained abstinent from 4 weeks onwards up to six months
3. We will also measure tobacco use, e.g. number of cigarettes smoked per day to estimate any reduction in tobacco use secondary to the intervention

Secondary outcome measures
1. Incidence of various adverse affects secondary to therapy
2. Economic outcomes assessed in terms of healthcare cost to get one person to stop smoking at four weeks. Healthcare cost will include the treatment cost, the average duration of health professionals' time spent with the patients during assessment, advice and counselling.
3. Process outcomes include:
3.1. The proportion of tobacco users who decide to quit and registered to receive 'five steps to quit' intervention
3.2. The proportion of people registered who continue follow-up for the full period planned

Overall study start date
01/12/2008

Completion date
30/11/2011

Eligibility

Key inclusion criteria
In each health centre, we will approach adult patients (greater than or equal to 18 years, either sex), who cough for three or more weeks and are therefore suspected and screened for pulmonary tuberculosis.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1100

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/12/2008

Date of final enrolment
30/11/2011

Locations

Countries of recruitment
England

Pakistan

United Kingdom

Study participating centre
Nuffield Centre for International Health and Development
Leeds
United Kingdom
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Sponsor information

Organisation
International Development Research Centre (IDRC) (Canada)

Sponsor details
150 Kent Street
Constitutional Avenue
Ottawa
Canada
K1G 3H9

Sponsor type
Research organisation

Website
http://www.idrc.ca/index_en.html

ROR
https://ror.org/0445x0472

Funder(s)

Funder type
Research organisation

Funder Name
International Development Research Centre (IDRC) (Canada) (ref: 104825-002)

Alternative Name(s)
Centre de recherches pour le développement international, IDRC, CRDI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Canada

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	25/03/2010		Yes	No
Results article	results	07/05/2013		Yes	No