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

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
05/12/2008		[X] Protocol		
Registration date 17/03/2009	Overall study status Completed	Statistical analysis plan		
		[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

#### Contact name

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#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

# 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 LS2 9LJ

# 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