Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Sep 2021

Determining efficacy of smoke cessation program on quit Rate, immunological response and treatment outcome in new pulmonary tuberculosis patients: a clinical trial

Protocol summary

Summary

Tuberculosis (TB) is one of the main causes of death in the world, especially Asia. Much morbidity and mortality due to tuberculosis occur in developing countries which smoking it is very common in them. New research on various aspects of the relationship between smoking and tuberculosis protests has shown effect of smoking on clinical, bacteriological, treatment and recurrence of tuberculosis. Therefore, smoking is a significant risk factor for tuberculosis and tobacco control, so it is recommended to include smoke cessation intervention as a preventive intervention in tuberculosis control programs. This Randomized Clinical trial (RCT) will be conducted during 3 years at National Research Institute of Tuberculosis and Lung Disease (NRITLD) in Tehran. During the study, approximately 60 patients in each group should be studied. Thus, in total, 240 patients (60 patients in each arm) will be evaluated for this study.Patients will be randomly selected among new TB diagnosed Cases, who will be treated by DOTS regime. Smoking evaluation and cessation Counseling and will be offered to the Patients by Physician trained in Smoke Cessation. Patients will be divided randomly in to the intervention group and will receive related smoke cessation intervention. Patients will be followed for Smoke Cessation result at the end of second week, second, quarter and Sixth months. Immunologic evaluation included measurement of cytokine (IL-8) and Fogocytosis will be done at base line and at the end of fourth month. TB Treatment assessment will be done at the end of second, fourth and sixth months, base on negative sputum smear, in all of the study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013062613783N1**
Registration date: **2013-08-31, 1392/06/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-08-31, 1392/06/09

Registrant information

Name

Mahshid Aryanpur

Name of organization / entity

National Research Institute of Tuberculosis and Lung Disease

Country

Iran (Islamic Republic of)

Phone

+98 21 2610 9508

Email address

mahshidaryanpur@yahoo.com

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining efficacy of smoke cessation program on quit Rate, immunological response and treatment outcome in new pulmonary tuberculosis patients: a clinical trial

Public title
Determining efficacy of smoke cessation on tuberculosis treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: current manufactured cigarette smokers will be diagnosed with active pulmonary TB: either sputum smear-positive or smear-negative, based on classification from WHO treatment guidelines; classify under treatment Category I (new TB cases) ; patients of both sexes, aged 18 years and above; speaking the Persian language. Exclusion criteria: having extra pulmonary TB only (involving CNS, pericardium, adrenal etc) ; they have multi-drug resistant tuberculosis at diagnosis ; they are living with or newly diagnosed with HIV/AIDS ; they are active IV drug abuser ; they are classified as Category II (relapse, treatment failure, and treatment after default) or Category III (chronic TB) ;they fulfill the eligibility criteria, but unwilling to participate in the study or unable to understand the contents of the informed consent form.
Age
From **18 years** old to **90 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **240**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Research Institute of Tuberculosis and lung disease
Street address
Masih Daneshvari Hospital-Daar abad- Niavaran
City
Tehran
Postal code
19569-44413
Approval date
2013-04-30, 1392/02/10
Ethics committee reference number
sbmu1.rec1392.17

Health conditions studied

1

Description of health condition studied
tuberculosis
ICD-10 code
A15
ICD-10 code description
Respiratory tuberculosis, bacteriologically and histologically confirmed

Primary outcomes

1

Description
tuberculosis treatment outcome
Timepoint
2,4,6 months
Method of measurement
sputum smear

Secondary outcomes

1

Description
smoke cessation
Timepoint
2-4-6 months
Method of measurement
urine cotenine test

2

Description
Immunologic response(phagocytes capacity uptake and IL-8 amount)
Timepoint
3 months
Method of measurement
flow cytometry

Intervention groups

1

Description
Intervention group (cessation consultation and pharmacotherapy): smokers patients with pulmonary tuberculosis who are under Tb DOTS Treatment that

recieve smoke cessation program consultation and pharmacotherapy . Cessation consultation consist of advice , assist and arrange .Four counseling sessions will be held during the first two weeks .patients will also receive sustain release Bupropion -150 mg- BD for nine weeks which will be free of charge for them.

Category

Treatment - Drugs

2

Description

Intervention groups(Brief advice counseling): smokers patients with pulmonary tuberculosis who are under Tb DOTS Treatment that receive smoking cessation brief advice for three minute. This group will get a short brief advice; strongly and clearly advice to quit smoking, given the benefits of cessation and linking it with their current disease status by trained physician during their TB treatment in the first visit.

Category

Behavior

3

Description

Smoker Control Groups: smoker patients with pulmonary tuberculosis which are under Tb Treatment and age and sex of them are matched with intervention group. They do not receive any intervention.

Category

N/A

4

Description

Non Smoker Control Groups: Non smoker patients with pulmonary tuberculosis which are under Tb Treatment and age and sex of them are matched with intervention group. They do not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

National Research Institute of Tuberculosis and Lung Disease

Full name of responsible person

Mahshid Aryanpur

Street address

Masih Daneshvari Hospital -Daar Abad-Niavaran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Proffesor Mohammad Reza Masjedi

Street address

Daarabad-Niavaran_Tehran

City

Tehran

Grant name

1238006

Grant code / Reference number

1238006

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

National Research Institute of Tuberculosis and Lung Disease

Full name of responsible person

Mahshid Aryanpur

Position

MD-MPH

Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty