

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of zinc supplementation in improving pulmonary tuberculosis patients in Qom

#### Protocol summary

##### Summary

The objective of this randomized double blind trial is to investigate the effect of Zinc supplementation on the recovery and reduce the symptoms of tuberculosis . 100 newly patients with pulmonary tuberculosis after filling the informed consent forms and questionnaires are randomly divided into two groups . The patients in the intervention group will receive 30 mg zinc every 48 h for 6 months with TB drugs but the control group will receive placebo every 48 h with TB drugs.Clinical manifestations (Smear,chest radiography ) ,BMI and serum level of zinc ,copper ,iron ,urea,creatinine albumin, total protein,alkaline phosphatase ,SGOT,SGPT will take place in patients at the baseline ,2 month and 6 month and compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112178429N1**

Registration date: **2012-08-09, 1391/05/19**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-08-09, 1391/05/19

##### Registrant information

###### Name

Fatemeh Pourfallah

###### Name of organization / entity

Institute Pasteur of Iran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6640 2770

##### Email address

fpourfallah@pasteur.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Institute Pasteur of Iran

##### Expected recruitment start date

2012-01-21, 1390/11/01

##### Expected recruitment end date

2014-03-20, 1392/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of zinc supplementation in improving pulmonary tuberculosis patients in Qom

##### Public title

Effect of zinc supplementation on tuberculosis therapy

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria includes having tuberculosis and filling the informed consent Exclusion criteria includes getting diseases such as cancer, stroke, immiunosupprision diseases and not taking mineral supplement or placebo

##### Age

From **18 years** old to **60 years** old

##### Gender

Both

##### Phase

1-2

##### Groups that have been masked

*No information*

##### Sample size

Target sample size: **100**  
**Randomization (investigator's opinion)**  
Randomized  
**Randomization description**  
**Blinding (investigator's opinion)**  
Double blinded  
**Blinding description**  
**Placebo**  
Used  
**Assignment**  
Parallel  
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**  
Instiute Pasteur of Iran  
**Street address**  
Pasteur Sq  
**City**  
Tehran  
**Postal code**  
**Approval date**  
2010-09-23, 1389/07/01  
**Ethics committee reference number**  
3020/0201/90

## Health conditions studied

### 1

#### Description of health condition studied

Pulmonary tuberculosis  
**ICD-10 code**  
A15-A19  
**ICD-10 code description**  
infections due to Mycobacterium tuberculosis and Mycobacterium bovis

## Primary outcomes

### 1

#### Description

Stop fever  
**Timepoint**  
At the baseline ,2 month and 6 month later  
**Method of measurement**  
Physical exam

### 2

#### Description

Radiological signs  
**Timepoint**

At the baseline ,2 month and 6 month later  
**Method of measurement**  
Chest radiology

### 3

#### Description

Smear negative  
**Timepoint**  
At the baseline ,2 month and 6 month later  
**Method of measurement**  
Smear

### 4

#### Description

Stop coughing  
**Timepoint**  
At the baseline ,2 month and 6 month later  
**Method of measurement**  
Physical exam

## Secondary outcomes

### 1

#### Description

Serum Zinc  
**Timepoint**  
At baseline ,2 month and 6 month later  
**Method of measurement**  
Atomic Absorption

### 2

#### Description

Serum Copper  
**Timepoint**  
At baseline ,2 month and 6 month later  
**Method of measurement**  
Atomic Absorption

### 3

#### Description

Serum Fe  
**Timepoint**  
At baseline ,2 month and 6 month later  
**Method of measurement**  
RA 1000

### 4

#### Description

Serum ALK  
**Timepoint**  
At baseline ,2 month and 6 month later  
**Method of measurement**  
RA 1000

### 5

#### Description

Serum Albumin

**Timepoint**

At baseline ,2 month and 6 month later

**Method of measurement**

RA 1000

**6**

**Description**

Body Mass Index

**Timepoint**

At baseline ,2 month and 6 month later

**Method of measurement**

weight(kg)/height2 (m2)

**7**

**Description**

Serum SGPT

**Timepoint**

At baseline ,2 month and 6 month later

**Method of measurement**

RA 1000

**8**

**Description**

Serum SGOT

**Timepoint**

At baseline ,2 month and 6 month later

**Method of measurement**

RA 1000

**9**

**Description**

Serum total protein

**Timepoint**

At baseline ,2 month and 6 month later

**Method of measurement**

RA 1000

**Intervention groups**

**1**

**Description**

Dietary Zinc supplement ,30 mg( zinc) every 48 h for 6 month

**Category**

Treatment - Drugs

**2**

**Description**

Placebo every 48 h for 6 months

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Health Center of Qom

**Full name of responsible person**

Dr Bahareh Zare

**Street address**

Emam Ave.

**City**

Qom

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Institute Pasteur of Iran

**Full name of responsible person**

Dr Saeed Bozari

**Street address**

Pasteur Ave.

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Institute Pasteur of Iran

**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**

Institute Pasteur of Iran

**Full name of responsible person**

Dr Fatemeh Pourfallah

**Position**

Faculty member/ DVM, MPH

**Other areas of specialty/work**

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fpourfallah@pasteur.ac.ir  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Institute Pasteur of Iran  
**Full name of responsible person**  
Dr Fatemeh Pourfallah  
**Position**  
Faculty member/ DVM, MPH  
**Other areas of specialty/work**  
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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*