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

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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

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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