Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of Zinc as a supplemental therapy in the treatment of patients with pulmonary tuberculosis

Protocol summary

Summary

The aim of this clinical trial is to evaluate the effect of zinc supplement on the pulmonary tuberculosis patients' outcome. Design: A double blind clinical trial will be conducted. 90 smear positive pulmonary tuberculosis patients size will be included. Samples will be collected from referred patients to Hospital and three Sistan tuberculosis centers. Methods: The smear positive patients' blood will be collected for zinc level evaluation. Moreover their chest-X-Ray image will be collected. The patients will be divided randomly into two groups of Intervention (A) and control (B). The group A subjects (n=45) will be treated by 10cc of 0.5% zinc syrup (with standard module) once a day and in group B (n=45) will be received placebo syrup with same prescription. The blood zinc level and sputum smear will be evaluated again in the end of second, fourth and sixth months and smear changes and changes in serum zinc will be compared and analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110630729N1**
Registration date: **2016-12-26, 1395/10/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-26, 1395/10/06

Registrant information

Name

Donya Arefi

Name of organization / entity

Zabol University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 54 3223 0768

Email address

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Recruitment status

Recruitment complete

Funding source

Zabol University of Medical Sciences Deputy of Research and Technology

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Zinc as a supplemental therapy in the treatment of patients with pulmonary tuberculosis

Public title

Effects of Zinc in the treatment of patients with pulmonary tuberculosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All tuberculosis diagnosed patients with the age ranged between 10-60 years. Exclusion criteria: Any chromosomal disorders; allergy to zinc; chronic renal disease; any other supplement or placebo assumption; side effect appearance such as blurred vision, pulmonary edema, icter and severe gastrointestinal symptoms.

Age

From **10 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Zabol University of Medical Sciences and Health Services

Street address

Zabol University of Medical Sciences, Shahid Rajai Street, Zabol, Sistan and Baluchestan

City

Zabol

Postal code

Approval date

2016-10-22, 1395/08/01

Ethics committee reference number

zbmu.1.REC.1395.64

Health conditions studied

1

Description of health condition studied

Pulmonary tuberculosis

ICD-10 code

A15

ICD-10 code description

Respiratory tuberculosis, bacteriologically and histologically confirmed

Primary outcomes

1

Description

Sputum smear

Timepoint

Beginning of diagnosis and two months, four months and six months after diagnosis

Method of measurement

Sputum smear

Secondary outcomes

1

Description

Serum zinc level

Timepoint

Beginning of diagnosis and two months, four months and six months after diagnosis

Method of measurement

Serum zinc level in micrograms per liter

Intervention groups

1

Description

Treatment intervention will be conducted by using zinc sulfate syrup (250 mg dosage) (Iran Daroo company) which will be taken once a day (after dinner) for six months

Category

Treatment - Drugs

2

Description

and intervention with placebo will be conducted with placebo assumption once a day (after dinner) for six months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Dr Zahra Sepehri

Street address

Zabol-Zahedan highway، Rustam square

City

Zabol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zabol University of Medical Sciences and Health

Services

Full name of responsible person

Zahra Sepehri

Street address

Shahid Rajai Street , University of Medical Sciences

City

Zabol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zabol University of Medical Sciences and Health Services

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

Zabol University of Medical Sciences

Full name of responsible person

Donya Arefi

Position

PhD/researcher

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