

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Assess the effectiveness of vitamin D in the treatment of pulmonary tuberculosis

Protocol summary

Summary

After adjusting for age and gender in this study, 64 patients were randomly divided into two groups. Written consent from all patients before participation in the study will be taken. The trial group, along with the standard 6-month TB treatment, vitamin D (450000 units IM in a single dose therapy) received, and to Controls, along with standard treatment for TB placebo is given. A clinical evaluation of all patients before the plan is adopted including chest radiography, measurements of height, weight, blood samples (to measure levels of vitamin D, CBC, ESR, and CRP). Patients on days 14, 28, 42 and 56 after treatment by medical examination will be followed up. At each follow-up sputum from patients and blood samples are taken and measured their weight and blood parameters. The SF-12 questionnaire to assess the health of older adults treated by Persian standards used at the beginning and end of the second month of treatment, the treatment is completed.

General information

Acronym

Adjuvant therapy

IRCT registration information

IRCT registration number: **IRCT201407029855N5**

Registration date: **2014-07-25, 1393/05/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-07-25, 1393/05/03

Registrant information

Name

Aiasghar Farazi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 1278 6526

Email address

dr.farazi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assess the effectiveness of vitamin D in the treatment of pulmonary tuberculosis

Public title

Adjuvant treatment with vitamin D in tuberculosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with smear positive pulmonary tuberculosis; younger than 15 years for entry into the study; obtain informed consent Exclusion criteria: Patients who have medical complications during the follow-up study; patients who need to change during the study medication are routine tuberculosis; Patients who are suffering from systemic disease or other debilitating (Such as chronic liver disease, kidney disease, HIV, Malignancy etc); patients who have recently used of

vitamin D in any other reason; Patients taking vitamin D in the past have suffered side effects or drug allergy; Pregnancy; in patients who taking of vitamin D is prohibited

Age

From **15 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **64**

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

Arak University of Medical Sciences

Street address

School of Medicine, Sardasht, Arak

City

Arak

Postal code

Approval date

2014-03-16, 1392/12/25

Ethics committee reference number

92-157-8

Health conditions studied

1

Description of health condition studied

Tuberculosis

ICD-10 code

A-15.o

ICD-10 code description

Tuberculosis of lung, confirmed by sputum microscopy with or without culture

Primary outcomes

1

Description

Erythrocyte Sedimentation Rate

Timepoint

Weeks of 2,4,6,8

Method of measurement

With westergren method - millimeters per first hour

2

Description

C-Reactive Protein

Timepoint

Weeks of 2,4,6,8

Method of measurement

Latex method - 1+ to 4+

3

Description

Complete Blood Count

Timepoint

Weeks of 2,4,6,8

Method of measurement

Measurement of Hgb and WBC

4

Description

Improvement of patient's symptoms

Timepoint

Weeks of 2,4,6,8

Method of measurement

Check list

Secondary outcomes

1

Description

Improved quality of life

Timepoint

Day 0 and day 30 of treatment

Method of measurement

SF-12 questionnaire

Intervention groups

1

Description

In this clinical trial study, in 32 patients as case group, along with routine anti-tuberculosis treatment for 6 months, vitamin D 450,000 IU intramuscularly in a single dose at the beginning of treatment will be given.

Category

Treatment - Drugs

2

Description

In this clinical trial study, in 32 patients as control group, along with routine anti-tuberculosis treatment for 6 months, placebo (Normal Saline) intramuscularly in a single dose at the beginning of treatment will be given.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Aliasghar Farazi

Street address

Department of infectious diseases, Valiasr Hospital, Arak

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Davood Hekmatpoo

Street address

School of Medicine, Sardasht, Arak

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Aliasghar Farazi

Position

Assistant Professor

Other areas of specialty/work

Street address

Department of Infectious Diseases, Valiasr hospital, Arak

City

Arak

Postal code

Phone

+98 86 3224 1411

Fax

Email

farazialiasghar@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Aliasghar Farazi

Position

Associate Professor

Other areas of specialty/work

Street address

Department of Infectious Diseases, Valiasr Hospital, Arak

City

Arak

Postal code

Phone

+98 86 3224 1411

Fax

Email

farazialiasghar@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Aliasghar Farazi

Position

Associate Professor

Other areas of specialty/work

Street address

Department of Infectious Diseases, Valiasr Hospital, Arak Arak Markazi Iran, Islamic Republic Of

City

Postal code

Phone

+98 86 3224 1411

Fax

Email

farazialiasghar@yahoo.com

Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty