

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Randomized, Double-Blind, Placebo-Controlled Trial of L-Arginine Supplementation for the treatment of pulmonary Tuberculosis

Protocol summary

Summary

This study aimed to assess the efficacy of L-arginine supplementation for treatment of pulmonary tuberculosis, that designed as a randomized, double-blind, placebo-controlled trial. In this study, 60 new smear positive patients (30 patients in the case group, 30 patients in the control group), of 10 health care centers in Central Province randomly are selected and After obtaining informed consent , patients randomly will be divided into two groups, in case group is given The standard treatment of TB with L - arginine (2 g per day for 30 days) and in Control group , along with standard TB treatment is given placebo (2 g per day for 30 days). Baseline clinical evaluation of all patients before the plan is including chest radiography, weight measurement, and check of CBC, ESR, and CRP. The Patients at days 14, 28, 42 and 56 after treatment are followed. the collected data analyzed by spss(version 19) software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211179855N2**
Registration date: **2013-01-10, 1391/10/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-10, 1391/10/21

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

2012-12-21, 1391/10/01

Expected recruitment end date

2013-08-22, 1392/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized, Double-Blind, Placebo-Controlled Trial of L-Arginine Supplementation for the treatment of pulmonary Tuberculosis

Public title

Effectiveness of L-Arginine supplementation for treatment of patients with pulmonary tuberculosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: adults over 15 years ; New cases of positive sputum smear
Exclusion criteria: pregnant women ; aged under 15 years , ; patients who During the past month received L-arginine ; Sensitivity to L - arginine

Age

From **15 years** old to **99 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

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

Alam al hoda street , Arak , Iran

City

Arak

Postal code

Approval date

2012-09-30, 1391/07/09

Ethics committee reference number

91-132-8

Health conditions studied

1

Description of health condition studied

Tuberculosis

ICD-10 code

A15.0

ICD-10 code description

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

Primary outcomes

1

Description

Improved paraclinical tests

Timepoint

days of 14 , 28 , 42 , 56

Method of measurement

check of CRP

2

Description

Improved paraclinical tests

Timepoint

days of 14 , 28 , 42 , 56

Method of measurement

check of ESR

3

Description

Improved paraclinical tests

Timepoint

days of 14 , 28 , 42 , 56

Method of measurement

check of CBC

Secondary outcomes

1

Description

Improve of life quality

Timepoint

0 and 56

Method of measurement

standard questionairof GHQ-28

2

Description

accelerating weight gain

Timepoint

0 AND56

Method of measurement

Weight measurement

Intervention groups

1

Description

In case group Standard anti-tuberculosis treatment for 6 months plus l- arginine, 2 g daily in first month

Category

Treatment - Drugs

2

Description

In control group 6-month Anti-TB treatment plus placebo 2gram daily in first month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers in central province

Full name of responsible person

Aliasghar Farazi

Street address

Department of Infectious diseases,Vali asr hospital,
Arak ,Iran

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

Management of Research services,Sardasht, Arak
University of Medical Sciences

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

Ghazaleh Akbarifard

Position

Secretary of research Council

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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Contact

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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