Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 givenThe 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

Effectivenessof 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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Person responsible for updating data

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