

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation of the effects of vitamin C on reducing anti-Tuberculous hepatotoxicity

Protocol summary

Study aim

Determining the effect of oral vitamin C on liver toxicity and increasing the clinical effectiveness of anti-TB drugs

Design

A randomized, blinded clinical trial with control group,

Settings and conduct

The researcher, referring to the health centers, randomly placed the patients with positive tuberculosis in one of the three groups and the first tests were requested and one-month intervals of the tests are repeated two times. From the beginning of the study, for two months every two weeks Phone calls for hepatotoxic symptoms

Participants/Inclusion and exclusion criteria

Patients with newly diagnosed positive smear-positive pulmonary tuberculosis with a minimum age and from any race if they are satisfied with participation in the study without a history of liver disease, they started studying

Intervention groups

Three groups of 30 people are present in the study:
1. Control group receives placebo tablet once per day
2. The group receives 500 mg vitamin C per day
3. The group receives 1000 mg vitamin C per day
Patients receive their anti-tuberculosis drugs in the usual way

Main outcome variables

Reduce the symptoms and impairment of liver tests in taking vitamin C

General information

Reason for update

Acronym

Interventional

IRCT registration information

IRCT registration number: **IRCT20170904036060N2**

Registration date: **2018-05-30, 1397/03/09**

Registration timing: **retrospective**

Last update: **2018-05-30, 1397/03/09**

Update count: **0**

Registration date

2018-05-30, 1397/03/09

Registrant information

Name

naser vahdati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 8818

Email address

vahdatin@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Approved Budget Plans at Mashhad University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-04-19, 1397/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of vitamin C on reducing anti-Tuberculous hepatotoxicity

Public title

protective effect of vitamin C on hepatotoxicity of anti-Tuberculous drugs

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pulmonary and non pulmonary tuberculosis documented by sputum acid-fast smear, pathologic confirmation willingness to participate in the study

Exclusion criteria:

sign of acute or chronic liver disease according to history, physical examination and preliminary lab data

Age

From **18 years** old to **99 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, responsible for filling out questionnaires and collecting data, health authorities at the centers were blinded to the three groups

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Imam Reza Hospital, Bahar Street

City

Mashhad

Province

Razavi Khorasan

Postal code

38411538-051

Approval date

2015-11-07, 1394/08/16

Ethics committee reference number

IR.MUMS.REC.1394.485

Health conditions studied

1

Description of health condition studied

Protective effect of vitamin C on hepatotoxicity of tuberculosis drugs

ICD-10 code

A15.0

ICD-10 code description

Tuberculosis of lung

Primary outcomes

1

Description

Disorders of the liver enzymes

Timepoint

Measure liver enzymes before the onset of intervention, one month after the start and two months after the start

Method of measurement

Examination of blood samples

Secondary outcomes

1

Description

Clinical symptoms and signs of hepatic toxicity

Timepoint

The beginning of the study. A month later. Two months later

Method of measurement

Liver test

2

Description

Sperm smear negative for TB

Timepoint

Second month

Method of measurement

Sample sputum examination for tuberculosis

Intervention groups

1

Description

First intervention group: Receiving 500 milligrams of vitamin C per day for two months

Category

Treatment - Other

2

Description

Intervention group2:: Receiving one gram of vitamin C per day for two months

Category

Treatment - Other

3

Description

Control group: Receives a placebo tablet (similar to vitamin C tablets) daily for 2 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers in Mashhad

Full name of responsible person

Mahnaz Amini

Street address

Imam Reza Hospital. Imam Reza Square

City

Mashhad

Province

Razavi Khorasan

Postal code

3845 6179

Email

aminim@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Naser Vahdati Mashhadiyan

Street address

Azadi Square. Pharmaceutical Faculty

City

Mashhad

Province

Razavi Khorasan

Postal code

136591775

Email

Vahdatin@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahnaz Amini

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work**Street address**

Bahar street.Imam Reza hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

00

Fax**Email**

aminim@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Pharmacy

Full name of responsible person

Nasser Vahdati Mashhadian

Position

PhD of toxicology from the University of Guildford,UK

Latest degree

Ph.D.

Other areas of specialty/work**Street address**

Mashhad University of Medical Sciences.Faculty of Pharmacy

City

Mashhad

Province

Razavi Khorasan

Postal code

9177513651

Phone

00

Fax**Email**

Vahdatin@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Elnaz Samadi

Position

Associate

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Emam Reza hospital.Imam Reza Square. Spring Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9177765661

Phone

00

Fax**Email**

samadise931@mums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available