

# 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