

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Evaluation of efficacy of “Ziziphus Vulgaris” formula to prevent “drug induced liver enzyme disorder” in pulmonary tuberculosis Patients

#### Protocol summary

##### Study aim

Evaluation of efficacy of "Ziziphus Vulgaris" formula to prevent “drug induced liver enzyme disorder” in pulmonary tuberculosis patients

##### Design

Double blind randomized clinical trial (block randomization); Sample size: 70; Drug group: 35, placebo group: 35.

##### Settings and conduct

All patients that referring to health centers in Golestan province, who are diagnosed as new pulmonary tuberculosis that must be treated by DOTs protocol entering the study. If they have criteria for entering the study, they will be introduced to the researcher. After initial liver tests, interventions begin for 4 weeks. At 14 and 28, liver tests are re-measured. During the study, patients can be contact to researcher if they have any questions or problems.

##### Participants/Inclusion and exclusion criteria

Entering: Declaration of written consent; Age from 30 to 65 years; A new diagnosis of pulmonary tuberculosis ; No relapse or drug resistance; No history of HIV-positive; No history of renal failure; No history of all types of acute, chronic and alcoholic hepatitis; No history of cirrhosis; No Pregnancy and lactation. Non-entering: Patients under treatment with other herbal supplements; Lack of appropriate verbal communication; Patients with Oral intolerance; No tendency to take herbal medicine; No tendency to consume syrup.

##### Intervention groups

Drug group: Jujube syrup, with a dose of 10 cc twice daily (morning fasting and night before bedtime) for 4 weeks. Placebo group: Placebo syrup, with a dose of 10 cc twice daily (morning fasting and night before bedtime) for 4 weeks. For each groups, routine anti-TB treatment will be implemented in accordance with the DOTs Country Program.

##### Main outcome variables

Serum level of alanine aminotransferase, aspartate

aminotransferase and alkaline phosphatase.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181107041586N1**

Registration date: **2019-08-10, 1398/05/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-08-10, 1398/05/19**

Update count: **0**

##### Registration date

2019-08-10, 1398/05/19

##### Registrant information

##### Name

Seyedeh zahra Maddahi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3304 4001

##### Email address

z.madahi@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-21, 1398/04/30

##### Expected recruitment end date

2020-05-19, 1399/02/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Evaluation of efficacy of "Ziziphus Vulgaris" formula to prevent "drug induced liver enzyme disorder" in pulmonary tuberculosis Patients

### Public title

Evaluation of efficacy of "Ziziphus Vulgaris" formula to prevent "drug induced liver enzyme disorder" in pulmonary tuberculosis Patients

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Declaration of written consent of the volunteer for participation in the trial Age from 30 to 65 years A new diagnosis of pulmonary tuberculosis by an infectious disease specialist or a health center doctor No relapse or drug resistance No history of HIV-positive No history of renal failure No history of all types of acute and chronic and alcoholic hepatitis No history of cirrhosis No Pregnancy and lactation

#### Exclusion criteria:

Patients under treatment with other herbal supplements Lack of appropriate verbal communication Patients with Oral intolerance No tendency to take herbal medicine No tendency to consume syrup

### Age

From **30 years** old to **65 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

### Sample size

Target sample size: **70**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Patients referring to health centers diagnosed with TB by a doctor who have criteria for entry into the study are included in the study. 70 samples will be assigned to two groups using the Block Random allocation method. The sample allocation will be done using the software, and samples will be assigned in binary blocks, ie, random numbers for blocks from Through the application. Patients will be placed in two groups A and B using the Randomization Block. Group A is given to the group B and placebo. In order to hide the random allocation of the groups, the method of packet envelopes will be used. Then the envelopes are opened for the patient, and the treatment is determined.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Due to the similarity of the drug & placebo, after

randomization and allocation of subjects to the two groups of study, the drugs were placed in the box and encoded. In this way, the patient and expert assessor and researcher will not be aware from type of intervention. Jujube & placebo syrups are similar in appearance and concentration, and until the end of the data analysis, they will remain hidden from the study's participants and participants (double blind).

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ethic committee of Mazandaran University of Medical Sciences

##### Street address

Deputy of Research and Technology of Mazandaran University of Medical Sciences, Teacher Street, Teacher's Square

##### City

Sari

##### Province

Mazandaran

##### Postal code

48168-95474

#### Approval date

2019-05-18, 1398/02/28

#### Ethics committee reference number

IR.MAZUMS.REC.1398.220

## Health conditions studied

### 1

#### Description of health condition studied

drug-induced hepatotoxicity

#### ICD-10 code

K71.9

#### ICD-10 code description

Toxic liver disease, unspecified

## Primary outcomes

### 1

#### Description

Serum level of alanine aminotransferase

#### Timepoint

At the beginning of the study (before the intervention), The end of the second week and at the end of the intervention

**Method of measurement**

Biochemical tests

**2****Description**

Serum level of aspartate aminotransferase

**Timepoint**

At the beginning of the study (before the intervention),The end of the second week and at the end of the intervention

**Method of measurement**

Biochemical tests

**3****Description**

serum level of Alkalin phosphatase

**Timepoint**

At the beginning of the study (before the intervention),The end of the second week and at the end of the intervention

**Method of measurement**

Biochemical tests

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Patients are treated with jujube-based syrup for a month receiving 10 cc of the syrup two times a day, fasting morning and half an hour before bedtime. Routine anti-TB treatment will be implemented in accordance with the DOTs Country Program.

**Category**

Prevention

**2****Description**

Control group: The control group receives placebo syrup.Routine anti-TB treatment will be implemented in accordance with the DOTs Country Program.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Golestan Province Health Center

**Full name of responsible person**

Mahnaz Sheikhi

**Street address**

Golestan Province health center, Takhty Alley, 5 Azar street, Gorgan

**City**

Gorgan

**Province**

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**Postal code**

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**Phone**

+98 17 3215 0742

**Email**

Dszm5652@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Majid Saeedi

**Street address**

Deputy of Research and Technology of Mazandaran University of Medical Sciences, Teacher Street, Teacher's Square

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m.saeedi@mazums.ac.ir

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

Yes

**Title of funding source**

Sari 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Assie Jokar

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Center for Traditional Medicine and Complementary  
Medicine of mazandaran university; Khazar  
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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Seyedeh Zahra Maddahi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

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48168-95475

**Phone**

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**Email**

Dszm5652@gmail.com

**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**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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