Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 11 3304 4001

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Other areas of specialty/work
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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