Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

The evaluation effects of the Livercare tablet (combination of Milk Thistle, Dandelion, Barberry, Tumeric (Curcumin) and Artichoke) in the prevention of anti-tuberculosis drugs-induced hepatotoxicity

Protocol summary

Study aim
The evaluation effects of the Livercare tablet (combination of Milk Thistle, Dandelion, Barberry, Tumeric (Curcumin) and Artichoke) in the prevention of anti-tuberculosis drugs-induced hepatotoxicity

Design
A randomized controlled clinical trial with parallel groups, two blinded, randomized

Settings and conduct
Patients are selected from Al-Zahra Hospital in Isfahan and are not aware of the therapeutic content of the other group, and the researcher does not know the medication packages provided by the pharmacologist.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age range 20 to 65 Active pulmonary or extrapulmonary tuberculosis No first-line anti-tuberculosis drugs (isoniazid, rifampin, pyrazinamide) in all patients in the past 8 weeks and starting on treatment No known hepatotoxic drugs (sodium valproate, methotrexate and sulfonamides) No continuous use of acetaminophen No systemic glucocorticoids, supplements containing thistle, dandelion, barberry, turmeric or artichoke in the past 4 weeks Exclusion criteria: Patient dissatisfaction alcohol consumption liver disease Discontinue medication for any reason other than liver toxicity Patient Withdrawal from Study Continuation Not taking the study tablet for at least 3 consecutive days

Intervention groups
For the intervention group, Livercare tablets will be prescribed twice a day for 2 weeks at the same time as the anticonvulsants (isoniazid, rifampin and pyrazinamide). The control group will receive only standard anti-cellulite treatment with placebo. Prior to the administration of the antiplatelet drugs and interventions mentioned above and immediately after the intervention, 5 ml of venous blood was taken from each patient in fasting state to measure liver enzymes and bilirubin.

Main outcome variables
Hepatic Enzymes (AST, ALT, ALP), Bilirubin (Direct and Total)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171230038142N16**
Registration date: **2020-03-13, 1398/12/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-13, 1398/12/23**
Update count: **0**

Registration date
2020-03-13, 1398/12/23

Registrant information

Name
Khosro Tavakol

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3792 9134

Email address
tavakol@nm.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2020-07-22, 1399/05/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The evaluation effects of the Livercare tablet (combination of Milk Thistle, Dandelion, Barberry, Tumeric (Curcumin) and Artichoke) in the prevention of anti-tuberculosis drugs-induced hepatotoxicity

Public title
The evaluation effects of the Livercare tablet (combination of Milk Thistle, Dandelion, Barberry, Tumeric (Curcumin) and Artichoke) in the prevention of anti-tuberculosis drugs-induced hepatotoxicity
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range 20 to 65 Active pulmonary or extrapulmonary tuberculosis No first-line anti-tuberculosis drugs (isoniazid, rifampin, pyrazinamide) in all patients in the past 8 weeks and starting on treatment No known hepatotoxic drugs (sodium valproate, methotrexate and sulfonamides) No continuous use of acetaminophen No systemic glucocorticoids, supplements containing thistle, dandelion, barberry, turmeric or artichoke in the past 4 weeks
Exclusion criteria:
Patient dissatisfaction alcohol consumption liver disease Discontinue medication for any reason other than liver toxicity Patient Withdrawal from Study Continuation Not taking the study tablet for at least 3 consecutive days
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are selected from people with pulmonary or extrapulmonary tuberculosis referred to Alzahra Hospital in Isfahan. Forty-four of them will be randomly selected: In the first step, the patients will be selected sequentially. In the second step, randomized binary blocks are used, meaning that the first two individuals are eligible to form a block and then randomly assigned to the drug group and the control group to the placebo . The main drugs (Livercare) will then be given to the pharmacologist and will be ordered to make a placebo and then the original and placebo will be referred back to the researcher without being informed by the pharmacist about the originator or placebo. Two groups A and B are named, then two patients are randomly assigned to one A and the other to B and are decoded after completing the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients are not excluded from the therapeutic content of other groups. On the other hand, the main drugs (Livercare) are given to the pharmacologist and he will order the preparation of the placebo (the pharmacist) then the original drugs and the placebo will be referred back to the researcher without the researcher being aware of the original or the placebo. They were assigned to groups A and B and were then assigned to one of the A and one of the B patients on a randomized two-block basis.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave.
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2019-05-16, 1398/02/26
Ethics committee reference number
IR.MUI.MED.REC.1398.038

Health conditions studied

1

Description of health condition studied
Tuberculosis
ICD-10 code
A15
ICD-10 code description
Respiratory tuberculosis

Primary outcomes

1

Description
Hepatic Enzymes (AST, ALT, ALP)
Timepoint
Before and one week and two weeks after intervention
Method of measurement
blood test

2

Description
Bilirubin (Direct and Total)
Timepoint
Before and one week and two weeks after intervention
Method of measurement
blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: All patients receive standard dose (by weight) treatment with first-line drugs (isoniazid, rifampin and pyrazinamide).In addition, for the intervention group, Livercare tablets, made by Health Aid, contain sperm powder (500 mg), dandelion root powder (200 mg), barberry root powder (200 mg), turmeric powder (200 mg) and powder Artichoke (200 mg) is prescribed twice a day for 2 weeks at the same time as starting anti-cellulite drugs.. Prior to the administration of the antiplatelet medications and interventions mentioned above, 5 ml of venous blood was taken from each patient in fasting state to measure liver enzymes (AST, ALT, ALP) and bilirubin (direct and total). During the study, the patient is screened weekly by a physician, and in addition to examining the patient for symptoms of hepatotoxicity, the serum levels of these parameters are determined at each visit. Hepatotoxicity, by increasing the serum level of ALT or AST liver enzymes by more than 5 times the maximum value without a clinical sign or more than 3 times the maximum value with clinical symptoms (such as nausea, vomiting, loss of appetite, upper abdominal pain). And jaundice) are defined. In case of hepatotoxicity caused by antiproliferative drugs, the administration of these drugs will be stopped.
Category
Prevention

2

Description
Control group: All patients receive standard dose (by weight) treatment with first-line drugs (isoniazid, rifampin and pyrazinamide).The control group will receive only standard anti-cellulite treatment with placebo. Prior to the administration of the antiplatelet medications and interventions mentioned above, 5 ml of venous blood was taken from each patient in fasting state to measure liver enzymes (AST, ALT, ALP) and bilirubin (direct and total). During the study, the patient is screened weekly by a physician, and in addition to examining the patient for symptoms of hepatotoxicity, the serum levels of these parameters are determined at each visit. Hepatotoxicity, by increasing the serum level of ALT or AST liver enzymes by more than 5 times the maximum value without a clinical sign or more than 3 times the maximum value with clinical symptoms (such as nausea, vomiting, loss of appetite, upper abdominal pain). And jaundice) are defined. In case of hepatotoxicity caused by antiproliferative drugs, the administration of these drugs will be stopped.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital in Isfahan
Full name of responsible person
Mohammad Reza Yazdani
Street address
Al-Zahra Hospital, Sofah Boulevard.
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81746-73461
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ziba Farajzadegan
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Vice-Chancellor for Research of School of Medicine,. Isfahan University of Medical Sciences,. Hezar Jarib Ave.
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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Reza Yazdani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Reza Yazdani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Neda Abrishami

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Biostatistics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The information is shared two years after the results are

published.

When the data will become available and for how long

The information is shared two years after the results are published.

To whom data/document is available

Doctors and Infectious Diseases

Under which criteria data/document could be used

Comparison of the other treatment with the present one

From where data/document is obtainable

Send Mbn57m@gmail.com an email

What processes are involved for a request to access data/document

Send Mbn57m@gmail.com an email

Comments