Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the effect of the combination of coenzyme Q10, alpha-lipoic acid, and acetyl-L-carnitine compared to placebo in the prevention of anti-tuberculosis drugs-induced hepatotoxicity

Protocol summary

Study aim

Evaluating the effect of the combination of CoQ10, alpha-lipoic acid, and acetyl-L-carnitine in the prevention of hepatotoxicity in patients receiving anti-tuberculosis drugs

Design

Randomized, Parallel Group, Placebo-Controlled Clinical Trial

Settings and conduct

Patients who had inclusion criteria were randomly assigned to two groups of experimental and placebo. All patients received standard anti-TB regimen. The patients of experimental group used drug capsules, while the patients of placebo group received placebo capsules twice daily for 2 weeks. Serum levels of ALT, AST, ALP and total bilirubin were measured before the intervention and then weekly for to 2 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age ≥ 18 years old; pulmonary or extrapulmonary tuberculosis; taking first-line anti-TB drugs (Isoniazid, Rifampin and Pyrazinamide) Exclusion criteria: taking first-line anti-TB drugs within the last 8 weeks; use of known hepatotoxic drugs (e.g., sodium valproate, methotrexate, sulfonamides); regular use of acetaminophen; use of systemic glucocorticoids; use of any supplements containing CoQ10 or alpha-lipoic acid or L-carnitine within the last 4 weeks; use of alcohol; use of antioxidants (such as vitamins E and C); chronic liver or kidney disease; pregnancy; and lactation

Intervention groups

Experimental group: taking capsules containing the combination of CoQ10, alpha-lipoic acid, and acetyl-L-carnitine, twice daily concurrently with the initiation of standard anti-tuberculosis drug regimen, for 2 weeks Control group: taking placebo capsules, twice daily concurrently with the initiation of standard anti-tuberculosis drug regimen, for 2 weeks

Main outcome variables

1. Serum levels of ALT and AST and ALP 2. Serum level of total bilirubin 3. The number of patients with drug-induced liver injury

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150721023282N11**
Registration date: **2020-07-13, 1399/04/23**
Registration timing: **retrospective**

Last update: **2020-07-13, 1399/04/23**
Update count: **0**

Registration date

2020-07-13, 1399/04/23

Registrant information

Name

Rasool Soltani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date
2017-04-04, 1396/01/15
Actual recruitment end date
2018-09-22, 1397/06/31
Trial completion date
2018-09-22, 1397/06/31

Scientific title
Evaluation of the effect of the combination of coenzyme Q10, alpha-lipoic acid, and acetyl-L-carnitine compared to placebo in the prevention of anti-tuberculosis drugs-induced hepatotoxicity

Public title
Evaluation of the effect of the combination of coenzyme Q10, alpha-lipoic acid, and acetyl-L-carnitine in the prevention of anti-tuberculosis drugs-induced hepatic adverse effect
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age ≥ 18 years Pulmonary or extrapulmonary tuberculosis Taking first-line anti-TB drugs (Isoniazid, Rifampin, and Pyrazinamide) No use of first-line anti-TB drugs within the last 8 weeks
Exclusion criteria:
Use of known hepatotoxic drugs (e.g., sodium valproate, methotrexate, sulfonamides) Regular use of acetaminophen Use of systemic glucocorticoids Use of any supplements containing coenzyme Q10 or alpha-lipoic acid or L-carnitine within the last 4 weeks Alcoholism Use of antioxidant agents (e.g., vitamins E and C) Having chronic hepatic or renal disease Pregnancy Lactation
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Actual sample size reached: **87**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization was used for patients' allocation to the groups. For this, an online random number generator was used (available at: https://www.random.org/sequences) so that even and odd numbers were considered for experimental and placebo groups, respectively, and each patient, after inclusion, was assigned to the related group according to the determined sequence.
Blinding (investigator's opinion)
Double blinded
Blinding description
Drug and placebo capsules will be fully similar and packaged in similar containers. The patient, the prescriber (physician), data analyst, and the laboratory personnel will be blind to the content of containers and intervention type.
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
Hezar-Jerib Avenue, Vice-chancellery for research, Isfahan University of Medical Sciences, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2017-02-19, 1395/12/01
Ethics committee reference number
IR.MUI.REC.1395.3.929

Health conditions studied

1

Description of health condition studied
Anti-tuberculosis drugs-induced hepatotoxicity
ICD-10 code
K71
ICD-10 code description
Toxic liver disease

Primary outcomes

1

Description
Serum level of alanine aminotransferase (ALT)
Timepoint
Before the intervention and days of 7 and 14 of intervention
Method of measurement
Blood test

2

Description
Serum level of aspartate aminotransferase (ALT)
Timepoint
Before the intervention and days of 7 and 14 of intervention
Method of measurement
Blood test

3

Description
Serum level of alkaline phosphatase
Timepoint
Before the intervention and days of 7 and 14 of intervention
Method of measurement
Blood test

4

Description
Serum level of total bilirubin
Timepoint
Before the intervention and days of 7 and 14 of intervention
Method of measurement
Blood test

5

Description
The number of cases of drug-induced liver injury
Timepoint
End of intervention
Method of measurement
Based on defined criteria

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: oral capsules containing the combination of CoQ10 (200 mg) + alpha-lipoic acid (250 mg) + acetyl-L-carnitine (250 mg) manufactured by Vitacost cmpany, USA, twice daily, for 2 weeks, with standard 4-drug anti-TB therapeutic regimen including isoniazid 5 mg/kg + rifampin 10 mg/kg + ethambutol 15 mg/kg + pyrazinamide 25 mg/kg
Category
Prevention

2

Description
Control group: placebo capsules, manufactured by Isfahan faculty of Pharmacy, twice daily, for 2 weeks, with standard 4-drug anti-TB therapeutic regimen including isoniazid 5 mg/kg + rifampin 10 mg/kg + ethambutol 15 mg/kg + pyrazinamide 25 mg/kg
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Rasool Soltani
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Soffeh Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mehdi Nematbakhsh
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Hezar-Jerib Avenue, Isfahan University of Medical Sciences
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nematbakhsh@med.mui.ac.ir
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

Rasool Soltani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidentiality of patients' data

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