Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of the effectiveness of vitamin E on the levels of liver enzymes (ALT and AST) in patients with high-dose statins-induced hepatic failure

Protocol summary

Study aim
Evaluation of the effectiveness of vitamin E on the levels of liver enzymes (ALT and AST) in patients with high-dose statins-induced hepatic failure

Design
Phase 2 randomized double-blinded placebo parallel clinical trial on 60 patients Randomization using Randomaization.com

Settings and conduct
This study will perform in clinics affiliated with the Mashhad University of Medical Sciences. Patients are randomly assigned to vitamin E and placebo groups. Patients and the main researcher are unaware of the group assignment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients receiving high doses of statins (Atorvastatin with a dose of more than 40 mg or Rosuvastatin with a dose of more than 20 mg); Abnormalities in liver function tests (increased aminotransferase level equal to or more than 1.5 and less than 3 times the upper limit of the normal range); Consent to admission to the study; No previous medical history of liver disease or elevated aminotransferase before statin. Non-inclusion criteria: Receiving other drugs that may affect the increase of liver enzymes; Elevation of LFT equal to or greater than 3 times

Intervention groups
Patients receiving high doses of statins who have increased levels of aminotransferases (ALT or AST) equal to or more than 1.5 times and less than 3 times the upper limit of the normal range and will be treated with vitamin E tablets at a dose of 200 units once a day for 2 months.

Main outcome variables
Changes in ALT level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220516054874N10**
Registration date: **2023-08-11, 1402/05/20**
Registration timing: **prospective**

Last update: **2023-08-11, 1402/05/20**
Update count: **0**

Registration date
2023-08-11, 1402/05/20

Registrant information

Name
Vafa Baradaran Rahimi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3800 2301

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baradaranrv@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date
2024-08-22, 1403/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of vitamin E on the levels of liver enzymes (ALT and AST) in patients with high-dose statins-induced hepatic failure

Public title
Effectiveness of vitamin E on the levels of liver enzymes in patients with high-dose statins-induced hepatic failure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients receiving high doses of statins (Atorvastatin with a dose of more than 40 mg or Rosuvastatin with a dose of more than 20 mg) Abnormalities in liver function tests (increased aminotransferase level equal to or more than 1.5 and less than 3 times the upper limit of the normal range) Consent to admission to the study No previous medical history of liver disease or elevated aminotransferase before statin initiation
Exclusion criteria:
Receiving other drugs that may affect the increase of liver enzymes Elevation of LFT equal to or greater than 3 times
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

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

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
The blocked randomization method is used. The volume of each block will be four. Then the list of blocks is written and numbers assigned to them, for example (AABB(1)- BBAA(2)- BABA(3)- BAAB(4)), which will be 14 blocks according to the sample size of 56. Then random numbers between 1 and 14 are selected according to the randomization site Randomaization.com and finally, the treatment allocation list is determined based on the random numbers.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Using sealed envelopes Due to the use of a placebo similar to the intervention treatment, the investigator and the participants will not be informed of the assigned treatment, and the analyst will also be unaware of the assigned treatment for the two groups. Finally, after analyzing the data, the researcher who prepared the packages will reveal the codes A and B.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Imam Reza Hospital Educational, Research and Treatment Center, Mashhad
Street address
Imam Reza Hospital educational complex building, Imam Reza Hospital, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
Approval date
2023-05-22, 1402/03/01
Ethics committee reference number
IR.MUMS.IRH.REC.1402.060

Health conditions studied

1

Description of health condition studied
Hepatic failure
ICD-10 code
K72
ICD-10 code description
Hepatic failure, not elsewhere classified

Primary outcomes

1

Description
Changes in ALT levels
Timepoint
At the beginning of the study and after 8 weeks of treatment
Method of measurement
Laboratory kit

Secondary outcomes

1

Description
Changes in AST levels
Timepoint
At the beginning of the study and after 8 weeks of treatment
Method of measurement
Laboratory kit

2

Description
Changes in CBC diff
Timepoint
At the beginning of the study and after 8 weeks of treatment
Method of measurement
Laboratory kit

3

Description
Changes in lipid profile levels
Timepoint
At the beginning of the study and after 8 weeks of treatment
Method of measurement
Laboratory kit

4

Description
Changes in hs-CRP serum level
Timepoint
At the beginning of the study and after 8 weeks of treatment
Method of measurement
Laboratory kit

Intervention groups

1

Description
Intervention group: Patients receiving high doses of statins who have increased levels of aminotransferases (ALT or AST) equal to or more than 1.5 times and less than 3 times the upper limit of the normal range and treated with vitamin E tablets at a dose of 200 units once a day for 2 months.
Category
Treatment - Drugs

2

Description
Control group: Patients receiving high doses of statins who have increased levels of aminotransferases (ALT or AST) equal to or more than 1.5 times and less than 3 times the upper limit of the normal range and treated with placebo tablets with the same shape and size once a day for 2 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinics affiliated with Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mostafa Ahmadi
Street address
Ghaeem hospital, Ahmadabad Blvd, Mashhad
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Razavi Khorasan
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9138813944
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+98 51 3801 2739
Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Mouhebati
Street address
Qurashi Building, Next to Hoveyzeh Cinema, University Street, Mashhad
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9138813944
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Email
Ramresearch@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
Dr. Vafa Baradaran Rahimi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Ghaeem hospital, Ahmadabad Blvd, Mashhad
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Person responsible for scientific inquiries

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Person responsible for updating data

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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