Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

Comparison of effectiveness of L-carnitine, atorvastatin, L-carnitine+atorvastatin, and placebo on liver enzyme levels and liver stiffness of subjects with nonalcoholic steatohepatitis

Protocol summary

Summary

This is a double-blind randomized control trial designed to evaluate the effect of atorvastatin and L-carnitine on nonalcoholic steatohepatitis in a 2x2 factorial design. Patients aged between 20 and 60 years referring to a referral center in Tehran will be studied. 440 patients diagnosed as nonalcoholic steatohepatitis will be enrolled. The diagnosis is confirmed by steatosis reported in ultrasonography and elevated liver enzymes. Subjects with other liver disease or severe medical conditions are excluded. Subjects will be randomly assigned to one of four groups: atorvastatin 20 mg daily, L-carnitine 1 gr daily, atorvastatin 20 mg and L-carnitine 1 gr daily, and placebo. Subjects will be followed for 1 year. At the end of the study changes in liver enzyme levels and liver stiffness will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111204092N2**
Registration date: **2012-02-25, 1390/12/06**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-02-25, 1390/12/06

Registrant information

Name

Shahin Merat

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8241 5300

Email address

merat@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-04-03, 1391/01/15

Expected recruitment end date

2014-10-07, 1393/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of L-carnitine, atorvastatin, L-carnitine+atorvastatin, and placebo on liver enzyme levels and liver stiffness of subjects with nonalcoholic steatohepatitis

Public title

The effect of atorvastatin and L-carnitine in the treatment of nonalcoholic steatohepatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: ultrasonography showing evidence of hepatic steatosis; increased AST or ALT to above 1.5 times normal; age 20-60 years old. Exclusion Criteria: hepatitis B; hepatitis C; autoimmune hepatitis; genetic liver disease; alcohol ingestion greater than 40 gr per week; hypertension; diabetes mellitus; liver stiffness more than 7.9 KP; Not consenting to the study.

Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **440**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Digestive Disease Research Center
Street address
Shariati Hospital
City
Tehran
Postal code
14117
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
416/548

Health conditions studied

1

Description of health condition studied
Nonalcoholic steatohepatitis (NASH)
ICD-10 code
k75.81
ICD-10 code description
Nonalcoholic steatohepatitis (NASH)

Primary outcomes

1

Description
Liver stiffness
Timepoint
years 0 and 1
Method of measurement
FibroScan

2

Description
Liver enzymes (AST and ALT)
Timepoint
months 0, 1, 3, 6, 9, and 12
Method of measurement
Elisa

Secondary outcomes

1

Description
Muscular cramps
Timepoint
months 1, 3, 6, 9, 12
Method of measurement
Questionnaire

2

Description
Nausea
Timepoint
months 1, 3, 6, 9, 12
Method of measurement
Questionnaire

3

Description
Dyspepsia
Timepoint
months 1, 3, 6, 9, 12
Method of measurement
Questionnaire

4

Description
Compliance
Timepoint
months 1, 3, 6, 9, 12
Method of measurement
Questionnaire

Intervention groups

1

Description
Atorvastatin 20 mg daily for 12 months
Category
Treatment - Drugs

2

Description
L-carnitine 1 gr daily for 12 months
Category
Treatment - Drugs

3

Description
Atorvastatin 20 mg and L-carnitine 1 gr daily for 12 months
Category
Treatment - Drugs

4

Description
Placebo daily for 12 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Shahin Merat
Street address
N Kargar St.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Reza Malekzadeh
Street address
Shariati Hospital
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shahin Merat
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty