

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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

**Position**

Associate Professor

**Other areas of specialty/work**

**Street address**

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**Web page address**

**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*