Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

Effect of treatment with L-Carnitin versus no treatment on the stage of disease in patients with nonalcoholic fatty liver: a single blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of treatment with L-Carnitin versus no treatment on the stage of disease in patients with nonalcoholic fatty liver. Design: a single blind randomized clinical trial. Setting and conduct: The eligible patients who with nonalcoholic fatty liver refer to Shahid Beheshti Hospital during the study period will be enrolled into the trial. Inclusion criteria: Affected with nonalcoholic fatty liver. Exclusion criteria: Using methotrexate medication; viral hepatitis; hyperthyroidisms; hypothyroidisms; uncontrolled diabetes. Intervention group: Routine treatment plus oral L-Carnitin 1 gr per day for 6 months. Control group: Just routine treatment. Primary outcome: Assessing the stage of disease before and 6 months after treatment using liver sonography. Secondary outcome: Assessing liver enzymes before and 6 months after treatment using laboratory tests. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. Therefore, the trial will be run as single blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610069014N121**
Registration date: **2016-10-08, 1395/07/17**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-10-08, 1395/07/17

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of treatment with L-Carnitin versus no treatment on the stage of disease in patients with nonalcoholic fatty liver: a single blind randomized clinical trial

Public title

Effect of treatment with L-Carnitin versus no treatment on the stage of disease in patients with nonalcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Affected with nonalcoholic fatty liver.
Exclusion criteria: Using methotrexate medication; viral hepatitis; hyperthyroidisms; hypothyroidisms; uncontrolled diabetes.
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. Therefore, the trial will be run as single blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
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Postal code
6517838695
Approval date
2016-08-06, 1395/05/16
Ethics committee reference number
IR.UMSHA.REC.1395.254

Health conditions studied

1

Description of health condition studied
nonalcoholic fatty liver
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Assessing the stage of disease
Timepoint
before and 6 months after treatment
Method of measurement
using liver sonography

Secondary outcomes

1

Description
Assessing liver enzymes
Timepoint
before and 6 months after treatment
Method of measurement
using laboratory tests

Intervention groups

1

Description
Routine treatment plus oral L-Carnitin 1 gr per day for 6 months
Category
Treatment - Drugs

2

Description
Just routine treatment
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Saed Karimdadi
Street address
Shahid Beheshti Hospital, Eram Ave.
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
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Hamadan University of Medical Sciences, Shahid Fahmideh 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
Vice-chancellor for Research the Technology, Hamadan 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

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Person responsible for updating data

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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