

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan  
University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### 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**

Hamadan

##### **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**

Hamadan

## 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

**Street address**

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

**City**

Hamadan

**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

**Contact****Name of organization / entity**

Shahid Beheshti Hospital

**Full name of responsible person**

Saed Karimdadi

**Position**

Medical Student

**Other areas of specialty/work****Street address**

Shahid Beheshti Hospital, Eram Ave.

**City**

Hamadan

**Postal code****Phone**

+98 81 3838 0283

**Fax****Email**

saedkid@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shahid Beheshti Hospital

**Full name of responsible person**

Dr Mayam Hassan Zarini

**Position**

Internist

**Other areas of specialty/work****Street address**

Shahid Beheshti Hospital, Eram Ave.

**City**

Hamadan

**Postal code****Phone**

+98 81 3838 0283

**Fax****Email**

Mhzarrini@sums.ac.ir

**Web page address**

## Person responsible for updating data

**Contact****Name of organization / entity**

Department of Epidemiology

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Associate Professor

**Other areas of specialty/work****Street address**

School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

**Fax****Email**

poorolajal@umsha.ac.ir

**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*