

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

L-carnitine effect in the treatment of non alcoholic fatty liver disease in typ 2 diabetic patients and comparision with placebo

Protocol summary

Summary

The aim of this study is investigate the effect of l-carnitin administration in the type2 diabetic patient with non alcoholic fatty liver disease and comparision with the plasebo. This study will be randomized and double blind trial. Inclusion criteria: Known case of diabetic type2: serum level of alanin aminotranspherase and aspartat aminotranspherase more than 2time of normal: high serum level of triglicirid and cholestrol level: ultrasonograghy evidences of fatty live. Exclusion criteria: any causes of increasing liver enzymes such as viral infections: hemochromatosis :alfa 1 anti tripsin dificiencie: Wilson's disease: autoimmune diseases: drinking (20 and 10 grams per day for men and women, respectively). 30 Patient will selected among patients referring to Gastroentrolology cliic of Jundishapur University of Medical Sciences and will divided equally in two intervention or control group. The patients in the intervention group will be received 750 mg l-carnitin every 8 hours for 3 months and in control group will received placebo every 8 hours forthree months. Main outcome measures are changes in aminotransferase serum level and triglicirid and cholestrol level and the grade of fatty liver determined by ultrasonography.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014020316348N2**

Registration date: **2014-03-10, 1392/12/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-10, 1392/12/19

Registrant information

Name

Mahmod Chobineh

Name of organization / entity

Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1375 7274

Email address

chobineh.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Gastroentrolology center of Jundishapur University of Medical Sciences

Expected recruitment start date

2014-01-05, 1392/10/15

Expected recruitment end date

2014-04-04, 1393/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

L-carnitine effect in the treatment of non alcoholic fatty liver disease in typ 2 diabetic patients and comparision with placebo

Public title

L-carnitine effect in diabetic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Known case of diabetic type2 : serum level of alanin aminotranspherase and aspartat aminotranspherase more than 2time of normal: and high

level of triglicerid and cholestrol level : ultrasonography evidences of fatty live. Exclusion criteria: any causes of increasing liver enzymes such as viral infections: hemochromatosis :alfa 1 anti tripsin dificiency:Wilson's disease: autoimmune diseases: drinking (20 and 10 grams per day for men and women, respectively)

Age

From **14 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

School of Medicine, Ahwaz Jundishapur University of Medical Sciences

Street address

Jundishapur University of Medical Sciences, Golestan Street -

City

ahwaz

Postal code

61355393

Approval date

2013-12-21, 1392/09/30

Ethics committee reference number

ajums.rec.1392.199

Health conditions studied**1****Description of health condition studied**

non alcoholic fatty liver disease

ICD-10 code

K76.1

ICD-10 code description

Other specified inflammatory liver diseases

Primary outcomes**1****Description**

Liver aminotransferase

Timepoint

Before intervention and three months after initiation of the intervention

Method of measurement

Eliza

Secondary outcomes**1****Description**

Serum level of triglicerid and cholestiril

Timepoint

Before intervention and three months after initiation of the intervention

Method of measurement

Eliza

2**Description**

Fasting blood glucos test

Timepoint

Before intervention and three months after initiation of the intervention

Method of measurement

Eliza

Intervention groups**1****Description**

IN intervention group: 750 mg L- carnitine, three times a day for three months

Category

Treatment - Drugs

2**Description**

IN control group: plasebo three times a day for three months

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Gastroentrology Clinic, Ahwaz Jundishapur Medical

School
Full name of responsible person
Chobineh Mahmood
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gastroentorology Recerch Center, Ahwaz Jundishapur
Medical School
Full name of responsible person
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Street address
Gastroentorology Recerch Center, Ahwaz Jundishapur
Medical School
City
Ahwaz

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**
Yes

Title of funding source

Gastroentorology Recerch Center, Ahwaz Jundishapur
Medical School

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
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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)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty