Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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 dificience؛ 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 Gastroentrology cliic of Jundishapur University of Medical Sciences and will divided equaly 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

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Jundishapur University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Gastroentrology 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 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 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 triglicirid and cholestril

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 Mahmod
Street address
Imam Khomini hospital, Azadegan Blvd
City
Ahwaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gastroentrology Recerch Center, Ahwaz Jundishapur Medical School
Full name of responsible person
Alavinehzad Pejman,Dr
Street address
Gastroentrology 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
Gastroentrology 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
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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