Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

The L-carnitine effect in the treatment of non alcoholic fatty liver disease

Protocol summary

Summary

The aim of this study was to investigate the effect of l-carnitin administration in the patient with non alcoholic fatty liver disease. In this randomized, double blind trial, eighty patients suffering from fatty liver disease were selected among patients referring to Sheikh Al-Raeis clinic in Tabriz, and assigned into intervention or control group. The patients in both groups were strongly recommended to do exercise and follow a weight loss and low fat diet. The patients in the intervention group received 500mg L carnitin, every 12 hours for 6 months while those in the control group didn't receive any drug. Main outcome measures are changes in aminotransferase serum level and the grade of fatty liver determined by ultrasonography.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102235893N1**
Registration date: **2011-07-30, 1390/05/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-07-30, 1390/05/08

Registrant information

Name
Arezo Judaki
Name of organization / entity
Tabriz University of Medical Science
Country
Iran (Islamic Republic of)
Phone
+98 41 1334 7554
Email address
judakia@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2010-12-31, 1389/10/10

Expected recruitment end date

2011-03-01, 1389/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The L-carnitine effect in the treatment of non alcoholic fatty liver disease

Public title

The L-carnitine effect in non alcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: serum level of alanin aminotranspherase and aspartat aminotranspherase more than 40mg, ultrasonograghy evidences of fatty liver Exclusion criteria: overt diabetes, TG serum over 500mg, other causes of increasing liver enzymes such as viral infections, hemochromatosis , Wilson's disease, autoimmune diseases, drinking (20 and 10 grams per day for men and women, respectively)

Age

From **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences

Street address
University Central Building, Golgasht St., Azadi Ave., Tabriz

City
Tabriz

Postal code
5165665811

Approval date
2010-12-30, 1389/10/09

Ethics committee reference number
5/4/7882

Health conditions studied

1

Description of health condition studied
non alcoholic fatty liver disease

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Serum level of alanine aminotransferase

Timepoint
Before intervention and six months after initiation of the intervention

Method of measurement
measuring serum level

Secondary outcomes

1

Description
Serum level of aspartate aminotransferase

Timepoint
Before intervention and six months after initiation of the intervention

Method of measurement
by serum level measurement

2

Description
fatty liver grading

Timepoint
befor intervention and six months after initiation intervention

Method of measurement
by ultasonography

Intervention groups

1

Description
IN intervention group: 500mg L- carnitine, two times a day, as well as recommendation for exercise, weight loss and low fat diet, for six months

Category
Treatment - Drugs

2

Description
Contol group: recommendations for exercise, weight loss, and low fat diet for 6 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Sheikh Al-Raeise Clinic

Full name of responsible person

Street address
Corner of Jodeiri Street, Azadi Avenue, Tabriz

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gasrtoenterology Research Centre Of Imam Reza Hospital

Full name of responsible person
Arezo Judaki

Street address
University Street, Imam Reza Hospital, Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gasrtoenterology Research Centre Of Imam Reza Hospital
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
Tabriz University of Medical Sciences
Full name of responsible person
Arezo Judaki
Position
Fellowship Of Gasroentrology
Other areas of specialty/work
Street address
Gastroentrology Department, Imam Reza Hospital, University Street, Tabriz
City
Tabriz
Postal code
Phone
+98 41 1337 4290
Fax
Email
JUDAKIA@tbzmed.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz Universitu of Medical Science and Health Services
Full name of responsible person
Seyed Yaaghoob Moaddab
Position
Subspeciality In Gasrology
Other areas of specialty/work
Street address
Imam Reza Hospital, University Street, Tabriz
City
Tabriz
Postal code
Phone
+98 914 361 4684
Fax
Email
ymoaddab@yahoo.com
Web page address

Person responsible for updating data

Contact

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