

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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 aminotransferase and aspartat aminotransferase more than 40mg, ultrasonography 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

before 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

Gasroenterology 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 Gasroenterology

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

Gastroenterology Department, Imam Reza Hospital, University Street, Tabriz

City

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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

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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