

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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, 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**  
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**

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**

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 University 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*