Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Study of the Serum levels of miRNA-16, miRNA-21, miRNA-217 and effects of L-carnitine on their levels , TNF-α , TGF-β cytokines, Malondialdehyde and CRP in Nonalcoholic Steatohepatitis (NASH) patients under weight loss regimen

Protocol summary

Summary

The aim of this study is to investigate the Serum levels of microRNA-16, microRNA-21, microRNA-217 and effects of L-carnitine on their levels, Tumor Necrosis Factor-α, Tumor Growth Factor-β cytokines, Malondialdehyde and C-Reactive Protein in Nonalcoholic Steatohepatitis patients under weight loss regimen. Inclusion criteria: age between 18-65 years; BMI≥25 kg/m2, under weight loss regimen; ALT≥1.5 fold norma;l Sonography showing Nonalcoholic Steatohepatitis, Exclusion criteria: not willing to collaborate;viral hepatitis; taking Insulin ;blood lipid-lowering agents; Antiinflammatory drugs(stroid and non stroid)and antioxidant supplement; smoking cigarettes. In this parallel randomized controlled trial, 92 men and women with NASH. will be recruited from nutrition clinic of Imam Reza hospital of Mashhad University of Medical Science. Blood samples will be obtained after an overnight fast before and after the study. Plasma miRNA will be extracted with Mirvana kit and then Real time PCR will be done. Other variables also will be measured. 3-days 24-recalls will be obtained at first and at the end of the study. Intervention group receives 2000 mg of L-carnitine as 2 vials and other group receives 2 placebo vials,before the meals, for 12 weeks. agents ,Antiinflammatory drugs(stroid and non stroid)and antioxidant supplement ,smoking cigarettes. Blood samples will be obtained after an overnight fast before and after the study.Plasma miRNA will be extracted with Mirvana kit and then Real time PCR will be done. TNF-α , TGF-β cytokines, Malondialdehyde and CRP also will be measured. 3-days 24-recalls will be obtained at first and at the end of the study. Intervention group receives 2000 mg of L-carnitine as 2 vials and other group receives 2 placebo vials,before the meals, for 12 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212052602N8**
Registration date: **2013-02-04, 1391/11/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-02-04, 1391/11/16

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Affairs of Tehran University of Medical Sciences

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the Serum levels of miRNA-16, miRNA-21, miRNA-217 and effects of L-carnitine on their levels , TNF-α , TGF-β cytokines, Malondialdehyde and CRP in Nonalcoholic Steatohepatitis (NASH) patients under weight loss regimen

Public title

Effects of L-carnitine on genetic, inflammation and antioxidant factors in Nonalcoholic Steatohepatitis patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : age between 18-65 years; BMI≥25 kg/m2, under weight loss regimen ; ALT≥1.5 fold normal; Sonography showing Nonalcoholic Steatohepatitis ; Exclusion criteria: not willing toCollaborate; viral hepatitis; taking Insulin; blood lipid-lowering agents;Antiinflammatory drugs(stroid and non stroid) and antioxidant supplements; smoking cigarettes.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

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 public Health,Tehran University of Medical Sciences

Street address

School of public Health, Alvand street,Argentina Square

City

Tehran

Postal code

Approval date

2012-11-17, 1391/08/27

Ethics committee reference number

91-03-161-19463-69987

Health conditions studied

1

Description of health condition studied

Nonalcoholic steatohepatitis

ICD-10 code

K75.9

ICD-10 code description

Nonalcoholic steatohepatitis(NASH)

Primary outcomes

1

Description

TNF-α

Timepoint

At first of the study and 12th week

Method of measurement

labratory kit

2

Description

TGF-β

Timepoint

At first of the study and 12th week

Method of measurement

Sandwich Elisa

3

Description

Malondialdehide

Timepoint

At first of the study and 12th week

Method of measurement

Sandwich Elisa

4

Description

CRP

Timepoint

At first of the study and 12th week

Method of measurement

labratory kit

5

Description

miRNA-16

Timepoint

At first of the study and 12th week

Method of measurement

RT-PCR

6

Description

miRNA-21

Timepoint

At first of the study and 12th week

Method of measurement

RT-PCR

7

Description

miRNA-217

Timepoint

At first of the study and 12th week

Method of measurement

RT-PCR

Secondary outcomes

empty

Intervention groups

1

Description

. Intervention group receives 2000 mg of L-carnitine as 2 vials,before the meals, for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group receives 2000 mg of Placebo as 2 vials,before the meals, for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Nutrition clinic of Imam Reza hospital

Full name of responsible person

Dr. Mohsen Nematy

Street address

School Of Medicine, Ferdosi University of Medical Sciences, Azadi Square

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Tehran University of Medical Sciences

Full name of responsible person

Dr.Akbar Fotouhi

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Vice Chancellor for Research of Tehran University of Medical Sciences, Ghods Ave, Keshavarz Blv

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research of Tehran University of Medical Sciences

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

School of public Health,Tehran University of Medical Sciences

Full name of responsible person

Dr.Shirin Amiri Moghaddam

Position

MD/Ph.D Student

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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