Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

The effect of myoinositol supplementation on serum levels of Pro-oxidant Antioxidant Balance (PAB), leptin and adiponectin, nutritional status and appetite in patients with non-alcoholic fatty liver disease

Protocol summary

Study aim
to determine the effect of myoinositol supplementation on serum levels of Pro-oxidant Antioxidant Balance (PAB), leptin and adiponectin , nutritional status and appetite in patients with non-alcoholic fatty liver disease

Design
Double-blinded placebo-controlled randomized controlled trial

Settings and conduct
The volunteers being eligible to participate in the study will be randomly allocated into "Myo-inositol" or "Placebo" group and followed the intervention for 8 weeks. At the beginning and and after 8 weeks, 7 cc 12-14 hour fasting blood was taken and serum samples would be used to assess liver enzymes, leptin, adiponectin and PAB.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with NAFLD (grade 1 and 2) both sexes age 18-55 years BMI between 30-40 kg/m2 Exclusion criteria: Athlete, pregnancy, lactation and menopause Use of contraceptive pills and estrogen Smoking and alcohol drinking Use of any supplement or mediccations affecting liver function over last 3 months Diseases with similar pathogenesis tend to be pregnant

Intervention groups
The intervention group will take myo-inositol supplement (2 gr sachets of myo-inositol before lunch and dinner) and placebo group (2 gr sachets of maltodextrin before lunch and dinner) for 8 weeks. At the beginning of the study, both groups will be given nutritional recommendations.

Main outcome variables
Nutritional status (energy, macronutrients, micronutrients intake), Leptin and adiponectin status and their ratio, Pro-oxidant Antioxidant Balance (PAB) status, anthropometric indices (weight, BMI)- body composition (Amount and % of body FM, FFM), liver function (liver ultrasonography and enzyme levels of ALT, AST)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210530051441N2**
Registration date: **2022-03-12, 1400/12/21**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-12, 1400/12/21**
Update count: **0**

Registration date
2022-03-12, 1400/12/21

Registrant information

Name
Mohammad Reza Shiri Shahsavar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 28 3336 9581
Email address
nutshiri@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-03-11, 1400/12/20
Expected recruitment end date
2022-08-21, 1401/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of myoinositol supplementation on serum levels of Pro-oxidant Antioxidant Balance (PAB), leptin and adiponectin, nutritional status and appetite in patients with non-alcoholic fatty liver disease

Public title
The effect of myo-inositol supplementation on NAFLD

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18-55 years Body mass index = 30-40 Kg /m2 Willingness to cooperate Hepatic steatosis based on Grade 1 and 2 NAFLD disease

Exclusion criteria:
Athlete, pregnancy, lactation and menopause in women Smoking and drinking alcohol Adherence to a special diet or weight loss 3 months before the study Use of chemical or herbal medicines for weight loss, hepatotoxic (phenytoin, amoxifine, lithium), lipid-lowering (statins), Insulin sensitizer, corticosteroids and non-steroidal, anti-inflammatory medications and any dietary supplements for 3 months before the study History of weight loss surgery over the last year those with cardiovascular, hepatic, renal, intestinal, thyroid and parathyroid dysfunction, billiary, any known autoimmune diseases, PCOs, cancers and conditions with mal-absorption such as Sprue and Crohn Candidate or history of Liver transplant

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, random allocation will be performed using the r.allocation command in Stata/MP 17.0*64 software, which performs both stratification and blocking at the same time. Thus, 42 eligible patients will be classified into 8 stratas based on 3 variables: age, sex and BMI (age ("18-35" vs "36-50"), gender ("female" vs "male"), BMI ("30-35 Kg/m2" vs "35-40 Kg/m2")) and we will define these 8 stratas in the r.allocation command. Also, since we will have 2 intervention and placebo groups, we will define blocks with size 2, which will be generated automatically by the Stata software at the same time, and we will use the generated sequence for random allocation.

Blinding (investigator's opinion)
Double blinded

Blinding description
The person who packaged supplements/placebo will not be aware about the content and also has no role in the implementation and analysis of the data. None of the researchers or patients will be aware of the type of combination each person is receiving.

Placebo
Used

Assignment
Parallel

Other design features
Patients in both placebo and supplement groups will receive nutritional recommendations

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Qazvin university of medical science

Street address
Qazvin university of medical sciences, bahanor blv.

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Province
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Postal code
3419759811

Approval date
2021-11-30, 1400/09/09

Ethics committee reference number
IR.QUMS.REC.1400.340

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver

ICD-10 code
K76.0

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

Primary outcomes

1

Description
serum leptin

Timepoint
Baseline and 8 weeks after intervention

Method of measurement
ELISA method

2

Description
serum adiponectin
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
ELISA method

3

Description
Ratio of leptin to adiponectin
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
According to the formula

4

Description
Pro-oxidant Antioxidant Balance (PAB)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Enzymatic and chemical methods

5

Description
Body mass index (BMI)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
According to the formula

6

Description
Fat mass
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Using bioelectric impedance analyzer

7

Description
Energy, macronutrients and micronutrients intakes
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
a 3-days 24 hour- recall questionnaire at each phase will be completed and analyzed using Nutritionist 4 software

8

Description
Physical activity level
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Via short form of IPAQ questionnaire

9

Description
Appetite status
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Validated appetite questionnaire

10

Description
Weight
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
using Seca scale

11

Description
Fat Free mass
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Using body analyzer based on bioelectric impedance

Secondary outcomes

1

Description
Fatty liver grade
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Ultrasonigraphy

2

Description
Alanine aminotransferase (ALT)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
enzymatic method

3

Description
Aspartate aminotransferase (AST)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
enzymatic method

Intervention groups

1

Description
Intervention group: Patients in this group will receive myo-inositol supplement and nutritional recommendation

for 8 weeks. Two 2 gr sachet of myo-inositol powder will be asked to be dissolved in a glass of water and consumed twice a day 30 minutes before lunch and dinner. As there is no specific recommendation for NAFLD we use the American Diabetes Association that recommends consuming more fruits, vegetables, whole grains and less saturated fatty acids.

Category

Treatment - Drugs

2

Description

Placebo group: Patients in this group will receive placebo and nutritional recommendations for 8 weeks. Two 2 gr sachet of maltodextrin powder which will be asked to be dissolved in a glass of water and consumed twice a day 30 minutes before lunch and dinner.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Velayat hospital- Qazvin

Full name of responsible person
Mohammad Reza Shiri Shahsavar

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Qazvin University of Medical Sciences, Bahonar blv,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name
vice chancellor for research and technology of qazvin university of medical sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Qazvin university of medical sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Mohammad Reza Shiri Shahsavar

Position
assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

Contact

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Position
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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Zahra Alizadeh Zonouzi

Position

student

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Bachelor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data collected for the primary outcomes will be shared

When the data will become available and for how long

Access starting 12 months after publication

To whom data/document is available

The data will only be available for people working in academic institutions.

Under which criteria data/document could be used

The data of the present study will only be accessible by other researchers , for conducting meta-analysis

From where data/document is obtainable

Mrs.Zahra alizadeh zonouzi, Email address: z.alizadeh76@yahoo.com, cellphone number: 09388202522

What processes are involved for a request to access data/document

The applicant should provide a brief description of the aims and methods of his Meta-analysis . His request will be assessed and , if agreed, the data will be emailed to the applicant. All these procedures will take no longer than 15 days

Comments