Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of myo-inositol supplementation on nutritional status, cardiometabolic factors, liver function, oxidative stress, visfatin and hs-CRP levels, gene expression of insulin resistance pathway and HIF1α, NF-kB, TNF-α, Interleukin-1β and 6 in patients with non-alcoholic fatty liver disease.

Protocol summary

Study aim

Determining the effect myo-inositol supplementation on nutritional status, cardiometabolic factors, liver function, oxidative stress, visfatin and hs-CRP levels, gene expression of insulin resistance pathway and HIF1α, NF-kB, TNF-α, Interleukin-1β and 6 in patients with non-alcoholic fatty liver disease

Design

Double-blinded placebo-controlled RCT on 50 patients

Settings and conduct

Individuals were randomly allocated into myo-inositol or placebo groups. The duration of the trial will be 8 weeks .At the beginning of the study, both groups will be given nutritional recommendations.

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 birth control pills and estrogen Smoking and alcohol use special diet Use of medicines for weight loss Taking medications affecting liver function for 3 months before or during the study Diseases with similar pathogenesis Intention of getting pregnant

Intervention groups

The intervention group will take myo-inositol supplement (2 gram sachets of myo-inositol before lunch and dinner) and placebo group (2 gram 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), Cardiometabolic status (glucose-insulin-HbA1c-HOMA-IR score)- (TG-TC-HDL-C-LDL-C)-SBP,DBP) Oxidative status (GPx ، SOD ، MDA ، CAT, NO, PON1 aryl esterase activity,TAC), visfatin and hs-CRP levels, Expression of inflammatory and insulin resistance genes, anthropometric indices (weight, BMI ,WC, WHR, WHtR)- body composition (Amount and % of body FM, FFM), liver function (liver ultrasonography and enzyme levels of ALT, AST and liver fibrosis score

General information

Reason for update

due to the addition of some variables to the previously approved protocol as well as changes in the title, we request to update this protocol.

Acronym

IRCT registration information

IRCT registration number: **IRCT20100209003320N22**
Registration date: **2021-10-04, 1400/07/12**
Registration timing: **prospective**

Last update: **2023-05-17, 1402/02/27**
Update count: **1**

Registration date

2021-10-04, 1400/07/12

Registrant information

Name

Mehrangiz Ebrahimi mamagani

Name of organization / entity

Health & Nutrition faculty of Tabriz university of medical sciences

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-10-23, 1400/08/01
Expected recruitment end date
2022-04-21, 1401/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of myo-inositol supplementation on nutritional status, cardiometabolic factors, liver function, oxidative stress, visfatin and hs-CRP levels, gene expression of insulin resistance pathway and HIF1α, NF-kB, TNF-α, Interleukin-1β and 6 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 in the range of 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 Infertility treatment, taking oral contraceptive pills Smoking and alcohol use Adherence to a special diet 3 months before the study Use of chemical or herbal medicines for weight loss and use of hepatotoxic drugs such as phenytoin, amoxifine , lithium and antihypertensive drugs and lipid-lowering drugs (statins), insulin sensitiser medications Taking antibiotics or dietary supplements that affect the levels of liver enzymes History of weight loss surgery over the last year or rigid weight loss diets three months before the trial Use of corticosteroids and NSAIDs or any type of supplements for 3 months before or during the study Use of any multivitamin (vitamin E and folic acid, etc.), antioxidants (L-arginine, glutamine) and fish oil supplements for 3 months before or during the study those with cardiovascular disease, hepatic, renal, intestinal, thyroid and parathyroid dysfunction, billiary disease, known autoimmune diseases, PCOs, cancers and conditions with mal-absorption such as Sprue and Crohn Having symptoms of a recent infectious, inflammatory disease or recent surgery Candidate or history of Liver transplant Intention for pregnancy
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: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
A research assistant not otherwise involved in the study, will be randomly allocated 50 patients into one of the two experimental groups (1:1), using the Random allocation software (RAS) and randomized block procedure of size 3 (age (18-30 vs 31-50 years)- gender (female vs male) and BMI (<35 kg/m2 vs. ≥35 kg/m2)).
Blinding (investigator's opinion)
Double blinded
Blinding description
The person in charge of packaging myo-inositol and placebo supplements without knowing the content will determine the type of supplement or placebo that has no role in the implementation and analysis of the study 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
Ethic Committee of Tabriz University of Medical Sciences
Street address
Golgasht St., Attar Neishaboori Ave., Tabriz University of Medical Sciences, School of Nutrition & Food Sciences
City
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Province
East Azarbaijan
Postal code
5166614711
Approval date
2021-09-13, 1400/06/22
Ethics committee reference number
IR.TBZMED.REC.1400.567

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
Insulin
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
ELISA method

2

Description
HbA1C
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Chromatography

3

Description
Total cholesterol
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Enzymatic-colorimetric method using spectrophotometer

4

Description
Triglyceride
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
enzymatic-colorimetric method using spectrophotometer

5

Description
HDL-C
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Enzymatic-colorimetric method using spectrophotometer

6

Description
LDL-C
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
According to the formula

7

Description
HOMA-IR
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
According to the formula

8

Description
Superoxide dismutase (SOD)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Spectrophotometric method

9

Description
Malondialdehyde (MDA)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Spectrophotometric method

10

Description
Total Antioxidant Capacity (TAC)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Spectrophotometric method

11

Description
Glutathione peroxidase(GPX)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Spectrophotometric method

12

Description
Nitric oxide (NO)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Spectrophotometric method

13

Description
Catalase (CAT)
Timepoint
Baseline and 8 weeks after intervention

Method of measurement
Spectrophotometric method

14

Description
paraoxonase arylesterase - 1 (PON-1)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Spectrophotometric method

15

Description
HIF1α gene expression
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Real-time polymerase chain reaction (RT-PCR)

16

Description
Nuclear factor kappa-B (NF-kB) gene expression
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Real-time polymerase chain reaction (RT-PCR)

17

Description
Tumor necrosis factor alpha (TNF-α) gene expression
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Real-time polymerase chain reaction (RT-PCR)

18

Description
Interleukin-1-beta gene expression
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Real-time polymerase chain reaction (RT-PCR)

19

Description
Interleukin 6 gene expression
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Real-time polymerase chain reaction (RT-PCR)

20

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

21

Description
Waist circumference
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
measuring tape

22

Description
waist-to-hip ratio (WHR)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
According to the formula

23

Description
Waist to Height Ratio (WHtR)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
According to the formula

24

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

25

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

26

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

27

Description
Physical activity level
Timepoint
Baseline and 8 weeks after intervention
Method of measurement

Via short form of IPAQ questionnaire

28

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

29

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

30

Description
Serum albumin
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
using BROMOCRESOL GREEN

31

Description
Platelets count
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Using Coulter counter

32

Description
AMPK gene expression
Timepoint
Baseline and 8 weeks after the intervention
Method of measurement
Real-time polymerase chain reaction (RT-PCR)

33

Description
PDK gene expression
Timepoint
Baseline and 8 weeks after the intervention
Method of measurement
Real-time polymerase chain reaction (RT-PCR)

34

Description
AKT gene expression
Timepoint
Baseline and 8 weeks after the intervention
Method of measurement
Real-time polymerase chain reaction (RT-PCR)

35

Description
Visfatin
Timepoint
Baseline and 8 weeks after the intervention
Method of measurement
ELISA method

36

Description
hs-CRP
Timepoint
Baseline and 8 weeks after the intervention
Method of measurement
ELISA method

Secondary outcomes

1

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

2

Description
NAFLD fibrosis score
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
According to the formula

3

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

4

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. The supplement is: Sachet contains 2 grams of myo-inositol powder dissolved in a glass of water and consumed twice a day 30 minutes before lunch and dinner.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group will receive placebo and nutritional recommendations for 8 weeks. The placebo is: A sachet containing 2 grams of maltodextrin powder which will 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

School of Nutrition and Food Sciences

Full name of responsible person

Dr. Mehrangiz Ebrahimi-Mameghani

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Golgasht St. - Attar Neyshabouri St. - Tabriz University of Medical Sciences- School of Nutrition and Food Sciences

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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

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mehrangiz Ebrahimimamagani

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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Full name of responsible person

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student

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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

Ms.Sara Arefhosseini, E-mail address:arefhosseini.sa@gmail.com, cellphone number: 09354720098 and Somaye Rostami E-mail address:somyrostammi96@gmail.com, cellphone number:09142399475

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