Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of myo-inositol supplementation and placebo on the expression level of SIRT-1 pathway genes (SIRT-1, eNOS, NF-kB, LDLR, LOX-1, LXRα, ABCA1 and PCSK9) involved in atherosclerosis in peripheral blood mononuclear cells of patients with non-alcoholic fatty liver disease

Protocol summary

Study aim
Determining the effect of myo-inositol supplementation and placebo on the expression level of SIRT-1 pathway genes (SIRT-1, eNOS, NF-kB, LDLR, LOX-1, LXRα, ABCA1 and PCSK9) involved in atherosclerosis in peripheral blood mononuclear cells of patients with non-alcoholic fatty liver disease

Design
Double-blinded placebo-controlled RCT on 44 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 chemical or herbal medicines for weight loss Taking any supplement or 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
expression level of SIRT-1 pathway genes (SIRT-1, eNOS, NF-kB, LDLR, LOX-1, LXRα, ABCA1 and PCSK9) , lipid profile (TG-TC-HDL-C-LDL-C) anthropometric indices (weight, BMI), liver ultrasonography

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190724044322N2**
Registration date: **2022-04-18, 1401/01/29**
Registration timing: **prospective**

Last update: **2022-04-18, 1401/01/29**
Update count: **0**

Registration date
2022-04-18, 1401/01/29

Registrant information

Name
Neda Roshanravan

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3337 3958

Email address
roshanravann@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-10, 1401/02/20

Expected recruitment end date
2022-12-11, 1401/09/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of myo-inositol supplementation and placebo on the expression level of SIRT-1 pathway genes (SIRT-1, eNOS, NF-kB, LDLR, LOX-1, LXRα, ABCA1 and PCSK9) involved in atherosclerosis in peripheral blood mononuclear cells of 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 insulin sensitizer medications, antibiotics or any kind of supplements that may affect liver enzymes History of weight loss surgery over the last year or rigid weight loss diets three months before the trial Use of NSAIDs or any any multivitamin or 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 use of any antihypertensive drugs and lipid-lowering drugs (statins) and medications related to cardiovascular patients 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: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
A research assistant not otherwise involved in the study, will be randomly allocated 44 patients into one of the two experimental groups (1:1), using the Random allocation software (RAS) and randomized block for age, gender and BMI.
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
tabriz
Province
East Azarbaijan
Postal code
5166614711
Approval date
2022-02-02, 1400/11/13
Ethics committee reference number
IR.TBZMED.REC.1400.1139

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

2

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)

3

Description
Endothelial nitric oxide synthase (eNOS) gene expression
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Real-time polymerase chain reaction (RT-PCR)

4

Description
low density lipoprotein receptor (LDLR) gene expression
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Real-time polymerase chain reaction (RT-PCR)

5

Description
lectin-type oxidized LDL receptor 1 (LOX-1) gene expression
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Real-time polymerase chain reaction (RT-PCR)

6

Description
Liver X receptor alpha (LXR-alpha) gene expression
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Real-time polymerase chain reaction (RT-PCR)

7

Description
ATP Binding Cassette Subfamily A Member 1(ABCA1) gene expression
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Real-time polymerase chain reaction (RT-PCR)

8

Description
Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) gene expression
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Real-time polymerase chain reaction (RT-PCR)

Secondary outcomes

1

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

2

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

3

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

4

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

5

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

6

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

7

Description
LDL-C
Timepoint

Baseline and 8 weeks after intervention

Method of measurement

According to the formula

Intervention groups

1

Description

Intervention group: Patients in this group will receive oral myo-inositol (a water soluble six carbon alcoholic sugar) supplement and nutritional recommendation (at the beginning and during the study) 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.Individuals are also asked to return unused sachets at the end of each two weeks to determine compliance and measure weight.

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.Individuals are also asked to return unused sachets at the end of each two weeks to determine compliance and measure weight.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Heart Hospital

Full name of responsible person

Neda Roshanravan

Street address

Shahid Madani Heart Hospital; in front of the University Research and Development Complex; Daneshgah street

City

Tabriz

Province

East Azarbaijan

Postal code

5166615573

Phone

+98 41 3335 7767

Email

neda.roshanravan10@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

Golgash St., Attar Neishaboori Ave., Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

51666-14711

Phone

+98 41 3335 7582

Email

neda.roshanravan10@gmail.com

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

Neda Roshanravan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Shahid Madani Heart Hospital; in front of the University Research and Development Complex; Daneshgah street

City

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Province

East Azarbaijan

Postal code
5166615573
Phone
+98 41 3337 3958
Email
neda.roshanravan10@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Neda Roshanravan
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Shahid Madani Heart Hospital; Daneshgah street; in front of University Research and Development Complex; Tabriz; Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166615573
Phone
+98 41 3335 7767
Email
neda.roshanravan10@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Neda Roshanravan
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Shahid Madani Heart Hospital; Daneshgah street; in front of University Research and Development Complex; Tabriz; Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166615573
Phone
+98 41 3335 7767
Email
neda.roshanravan10@gmail.com

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
neda roshanravan neda.roshanravan10@gmail.com +98 914 371 0080
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