

# 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, LXR $\alpha$ , 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, LXR $\alpha$ , 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/m<sup>2</sup>  
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, LXR $\alpha$ , 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, LXR $\alpha$ , 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 / m<sup>2</sup> 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, amoxicifine , 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

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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

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

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##### Province

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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## Person responsible for updating data

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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

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