

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

The effect of L-arginine supplementation on the levels of antioxidative enzymes and inflammatory factors in patients with Metabolic dysfunction-associated steatotic liver disease(MASLD)

Protocol summary

Study aim

Determining the effect of L-arginine supplementation on inflammatory factors and oxidative stress indices in people with steatotic liver disease associated with metabolic disorders (MASLD)

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized. The sample size was 17 people in each group, including attrition: 22 people in each group. The data were analyzed using SPSS ver 19.

Settings and conduct

This study is a randomized double-blind controlled clinical trial on patients with metabolic disorder associated with steatotic liver disease (MASLD) referred to Razi Hospital and specialized clinics affiliated to Tehran University of Medical Sciences, which in a time interval It will be held in the fall of 1403 to the summer of 1404 in Tehran. Patients will be included in the study after being diagnosed by a specialist doctor from the Gastroenterology Clinic of Razi Hospital in terms of inclusion and non-inclusion criteria.

Participants/Inclusion and exclusion criteria

1) Patients with metabolic disorders associated with diagnosed steatotic liver disease without fibrosis and cap score below 310 and Metavir score below f1, which has been approved by a gastroenterologist 2) Age 30-55 3) BMI 25-35

Intervention groups

the intervention group will consume 3000 mg of arginine daily for 8 weeks. The arginine tablets are purchased from Karen B. All patients will be monitored for pill consumption with a daily checklist and recall messages

Main outcome variables

Glutathione peroxidase (GPX), Superoxide dismutase (SOD), C-reactive protein (CRP), Erythrocyte Sedimentation Rate (ESR)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230123057193N4**

Registration date: **2024-10-24, 1403/08/03**

Registration timing: **registered_while_recruiting**

Last update: **2024-10-24, 1403/08/03**

Update count: **0**

Registration date

2024-10-24, 1403/08/03

Registrant information

Name

Soraiya ebrahimpour-koujan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-22, 1403/08/01

Expected recruitment end date

2024-12-21, 1403/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of L-arginine supplementation on the levels of antioxidative enzymes and inflammatory factors in patients with Metabolic dysfunction-associated steatotic liver disease(MASLD)

Public title

The effect of L-arginine supplementation on the levels of antioxidative enzymes and inflammatory factors in patients with Metabolic dysfunction-associated steatotic liver disease(MASLD)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with metabolic disorder related to diagnosed steatotic liver disease without fibrosis and cap score below 310 and Metavir score below f1, which has been confirmed by a gastroenterologist. Age between 30-55 BMI 25- 35

Exclusion criteria:

pregnant and lactating chronic diseases such as cardiovascular, cancer, Alzheimer's, Parkinson's, and chronic kidney disease, history of stroke and heart attack, rheumatoid arthritis, diabetes, thyroid diseases, and other chronic diseases and menopause Based on the information provided by the individual Blood Pressure Medications Thyroid Medications corticosteroids drug Drugs affecting blood glucose levels Anti-inflammatory supplements Antioxidant supplements Omega 3 consumption Taking antibiotics, antivirals and antifungals Any history of alcohol and tobacco use

Age

From **30 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

The study subjects will be divided into blocks based on gender and BMI and then will be randomly divided into two intervention groups with arginine and placebo. 44 subjects will be randomly assigned using the RAS statistical software) (size 4) will be assigned to intervention and placebo groups, and patients will be placed in blocks of 4 based on BMI and gender. In this study, the participants are randomly placed in two intervention and placebo groups so that researchers can compare different treatments. Researchers and participants cannot arbitrarily play a role in assigning people to groups. Random allocation of people to the intervention or placebo group will be done by an experienced expert.

Blinding (investigator's opinion)

Double blinded

Blinding description

All subjects and researchers will be unaware of the existing grouping until the end of the study, and L-arginine supplement and placebo will be given to subjects once every 4 weeks by another person who has no knowledge of the research process. In order to evaluate the acceptance of the patients, a checklist will be prepared and given to the patients and they will be asked to record their daily consumption in it. In addition, in order to ensure the consumption of supplements, reminder messages will be sent to all patients every day

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Science

Street address

Keshavarz Boulevard-Qods Street

City

Tehran

Province

Tehran

Postal code

141556117

Approval date

2024-09-03, 1403/06/13

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1403.236

Health conditions studied

1

Description of health condition studied

Metabolic dysfunction-associated steatotic liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Erythrocyte sedimentation rate (ESR)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

ELISA assay

2

Description

C-reactive protein (CRP)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

ELISA assay

3

Description

Superoxide dismutase (SOD)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

ELISA assay

4

Description

Catalase

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

ELISA assay

5

Description

Glutathione peroxidase (GPX)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

ELISA assay

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive 3000 mg of arginine daily (3 tablets of 1000 mg) with water for 8 weeks. Arginine tablets are purchased from Karen. All patients will be monitored for pill consumption with a daily checklist and recall messages.

Category

Treatment - Drugs

2

Description

Control group: People in the placebo group will take a pill that is completely similar to the L-arginine supplement in terms of appearance, color and smell, daily in the same way for 8 weeks. Placebo pills are purchased from Karen Company. All patients will be monitored for pill

consumption with a daily checklist and recall messages.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Sorayia ebrahim pour koujan

Street address

Vahdat eslami street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research assistant of Tehran University of Medical Sciences

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?

No

Title of funding source

Research assistant of Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

sorayia ebrahim pour koujan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

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City

Tehran

Province

Tehran

Postal code**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available