

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of L-arginine supplementation on matabolic factors and stress oxidative indices in patients with Metabolic dysfunction-associated steatotic liver disease (MASLD): a double-blind randomized controlled clinical trial

Protocol summary

Study aim

The effect of L-arginine supplementation on matabolic factors and stress oxidative indices in patients with Metabolic dysfunction-associated steatotic liver disease (MASLD)

Design

Randomized clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 to 3 on 44 patients, RAS software was used for randomization.

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 2023 to the summer of 2024 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

Inclusion criteria: 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, age 30-55, BMI 25-35, both Exclusion criteria: Pregnancy, breastfeeding having history of malignancy, kidney stones, other chronic and inflammatory diseases. Taking antibiotics, antivirals and antifungals Use of antioxidants and omega3 in the last 3 months Any history of alcohol and tobacco use

Intervention groups

3000 mg L-arginine for 8 weeks, Placebo

Main outcome variables

Alanine transaminase, Aspartate aminotransferase, Low density lipoprotein, High density lipoprotein, Triglyceride,

Total cholesterol, Fasting blood sugar, Fasting blood insulin, Malondialdehyde, Homeostatic Model Assessment for Insulin Resistance, Homeostasis Model Assessment of β -cell function, Quantitative insulin sensitivity check index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230123057193N5**

Registration date: **2024-10-29, 1403/08/08**

Registration timing: **registered_while_recruiting**

Last update: **2024-10-29, 1403/08/08**

Update count: **0**

Registration date

2024-10-29, 1403/08/08

Registrant information

Name

Soraiya ebrahimpour-koujan

Name of organization / entity

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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 metabolic factors and stress oxidative indices in patients with Metabolic dysfunction-associated steatotic liver disease (MASLD): a double-blind randomized controlled clinical trial

Public title

The effect of L-arginine supplementation on metabolic factors and stress oxidative indices 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. BMI 25- 35 Age between 30-55

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 Blood Pressure Medications Taking antibiotics, antivirals and antifungals Any history of alcohol and tobacco use

AgeFrom **30 years** old to **55 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget sample size: **44****Randomization (investigator's opinion)**

Randomized

Randomization description

All subjects and researchers and healthcare personnel who are responsible for the care of patients will be unaware of the existing grouping until the end of the study; In such a way, the researcher and the person who

takes the sample, like the study participants, are unaware of which patient will receive the vitamin pill or the placebo. Patients are also unaware of the type of pill received. Drugs and placebos are coded by a person who is completely unaware of the study process, and this code is placed in an envelope that indicates whether it is a drug or a placebo code. One group will receive drug A and one group will receive drug B. Also, pills containing L-arginine and placebo, which have the same color, smell, and size as the vitamin pill, will be given to the study subjects every 4 weeks by another person who has no knowledge of the research process. Hence, this study will be a double-blind study. Placebo tablets contain starch and are completely similar to L-arginine tablets in terms of color, appearance and smell. Placebo tablets are also prepared by the same company that manufactures L-arginine.

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 da

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Science

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Qods Street, Keshavarz Boulevard

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1461884513

Approval date

2024-09-30, 1403/07/09

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1403.284

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

Alanine transaminase, Aspartate aminotransferase

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Elisa

2

Description

Low density lipoprotein, High density lipoprotein, Triglyceride, Total cholesterol

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Elisa

3

Description

Fasting blood sugar, Fasting blood insulin

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Elisa

4

Description

Malondialdehyde

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Elisa

5

Description

Homeostatic Model Assessment for Insulin Resistance, Homeostasis Model Assessment of β -cell function, Quantitative insulin sensitivity check index

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Using the formula

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 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

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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

Ali Akbari Sari

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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

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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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