Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
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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
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Sponsors / Funding sources

1

Sponsor
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Research assistant of Tehran University of Medical Sciences
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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
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Person responsible for updating data

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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