# 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**
**Name**
Soraiya ebrahimpour-koujan
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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**
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## Sponsors / Funding sources

**1**

**Sponsor**
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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
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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