Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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

Country
Iran (Islamic Republic of)

Phone
+98 21 2232 9521

Email address
ebrahimpour_s@sina.tums.ac.ir

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 matabolic 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 matabolic 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 individualBlood 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
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
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
Street address
Qods Street, Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
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
Street address
Vahdat eslami street
City
Tehran
Province
Tehran
Postal code
1199663911
Phone
+98 21 5563 0220
Email
nutri.seam1@gmail.com

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

Street address
Tehran University of Medical Sciences Headquarters, Qods Corner, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 81631
Email
office@tums.ac.ir
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
Street address
Razi Hospital, Razi Dead End, Vahdat Islami Square, Vahdat Islami Street,Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1199663911
Phone
+98 21 5563 0553
Email
nutri.seam1@gmail.com

Person responsible for scientific 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
Street address
Razi Hospital, Razi Dead End, Vahdat Islami Square, Vahdat Islami Street,Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1199663911
Phone
+98 21 5563 0553
Email
nutri.seam1@gmail.com

Person responsible for updating data

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
Street address
Razi Hospital, Razi Dead End, Vahdat Islami Square, Vahdat Islami Street,Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1199663911
Phone
+98 21 8670 5503
Email
nutri.seam1@gmail.com

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