

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Investigating the effect of L-arginine on patients with non-alcoholic fatty liver disease

Protocol summary

Study aim

Investigating the effect of L-arginine in alleviating patients with non-alcoholic fatty liver disease

Design

A clinical trial with two groups of drug intervention and placebo with parallel groups, double blind, phase 4 on 60 patients who are randomly assigned to the groups.

Settings and conduct

Patients with non-alcoholic fatty liver disease (referring to the gastroenterology clinic of Taleghani Hospital in Tehran) who were diagnosed by ultrasound will be included in the study. At the beginning of the study, all patients undergo AST, ALT, FIB-4, PLT and fibroscan tests. BMI of the patients will also be checked. Then, based on the principle of randomness, they are divided into two groups of 30 people. For the first group, lifestyle modification and L-arginine are prescribed at a dose of 2 grams per day, and for the second group, lifestyle modification and placebo are prescribed. This study will be double-blind so that the participants and the analyst are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients over 18 years old with non-alcoholic fatty liver disease. Exclusion criteria: drug complications, beginning pregnancy during the study.

Intervention groups

For the first group, lifestyle modification and L-arginine (perarin pars company) at a dose of 2 grams daily, and for the second group, lifestyle modification and placebo (perarin pars company) are prescribed.

Main outcome variables

Improvement of liver steatosis, improvement of paraclinical index of ALT, improvement of Fib-4

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230409057859N1**

Registration date: **2023-04-18, 1402/01/29**

Registration timing: **prospective**

Last update: **2023-04-18, 1402/01/29**

Update count: **0**

Registration date

2023-04-18, 1402/01/29

Registrant information

Name

Afsaneh Sharifian

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2243 2525

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-05, 1402/02/15

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of L-arginine on patients with non-alcoholic fatty liver disease

Public title

The effect of L-arginine in non-alcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with non-alcoholic fatty liver Patients over 18 years old

Exclusion criteria:

• pregnant women • Patients with liver cirrhosis • Patients with viral and autoimmune hepatitis • Patients with advanced heart and kidney diseases • Patients with celiac disease Wilson's patients

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned to two arms, using block randomization method. The block size is four, involving 3 patients (based on order's coming) which would generated by online block randomization software "Sealed Envelope". The list of random blocks will be placed in envelopes, daily would be opened by the staffs.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be single- blind, so that the analyzing researcher does not know which data is related to which patient, and the data related to the patients will be provided to him with the code, not with the name of the patient. Also, regarding the blinding of the participants, the general process of the study will be explained to them, but the patients will not know which group they will be in and which intervention (placebo or drug).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Gastroenterology and Liver Research Institute of Shahid Beheshti University of M

Street address

Arabi street, Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-03-11, 1401/12/20

Ethics committee reference number

IR.SBMU.RIGLD.REC.1401.036

Health conditions studied

1

Description of health condition studied

fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Improvement of hepatic steatosis

Timepoint

before the start of the intervention and 3 months after the intervention

Method of measurement

fibro scan

2

Description

Alanine Aminotransferease (ALT) allevation

Timepoint

before the start of the intervention and 3 months after the intervention

Method of measurement

blood test- biochemical marker

3

Description

Fibrosis Index -for liver based in 4 factors (Fib-4) alleviation

Timepoint

before the start of the intervention and 3 months after the intervention

Method of measurement

Mathematical formula fib-4

Secondary outcomes

1

Description

BMI alleviation
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
Height and weight ratio formula

Intervention groups

1

Description
Intervention group: The first intervention group will receive lifestyle modification and L-arginine drug (Perarin Pars Company) at a dose of 2 grams per day for 3 months.
Category
Treatment - Drugs

2

Description
Intervention group: The second intervention group will receive lifestyle modification and placebo (Perarin Pars Company) once a day for 3 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastroenterology and Liver Clinic, Taleghani Hospital, Tehran
Full name of responsible person
Mohammad Javad Ehsani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti 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?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hossein Rashvand
Position
Gastroenterologist assistant
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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the complete presentation of the results based on the data in the text of the article, and the preservation of the raw data, there are no plans to publish it.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

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

Title and more details about the data/document

The study protocol and clinical study report will be made available to other researchers. Also, the statistical analysis map and the codes used in the analysis are provided to statistical experts

When the data will become available and for how long

After publishing the article

To whom data/document is available

Researchers, professors and students in the field of gastroenterology

Under which criteria data/document could be used

For the purpose of use and guidance for further studies and if reference is mentioned

From where data/document is obtainable

corresponding author Hossein Rashvand
dr.h.rashvand@gmail.com

What processes are involved for a request to access data/document

Sending the request email to the responsible author and mentioning the reason for the request and how to use the data

Comments