Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effectiveness of ellagic acid on liver steatosis in patients with non-alcoholic fatty liver disease

Protocol summary

Study aim
Evaluation of the effectiveness of ellagic acid on liver steatosis in patients with non-alcoholic fatty liver disease

Design
Phase 2 randomized double-blinded placebo parallel clinical trial on 60 patients; randomization using Randomaization.com.

Settings and conduct
This study will perform in the clinics of Mashhad University of Medical Sciences. Patients are randomly assigned to Ellagic acid and placebo groups. Patients and the main researcher are unaware of the group assignment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 30-65 years old; body composition index between 25-35; diagnosis of liver steatosis by two-dimensional elastography (grade 2 and above); fatty liver patients with grade F0 and F1.
Exclusion criteria: viral hepatitis (especially hepatitis C); alcoholic fatty liver or consumption of alcohol; diseases such as Wilson's disease, hemochromatosis, celiac disease, cirrhosis, biliary obstruction and primary biliary cirrhosis; special nutritional conditions such as starvation, fasting, and intravenous feeding; smoker; breastfeeding or pregnancy; history of hypersensitivity to pomegranate and its products; diabetes; taking any kind of herbal supplements; fatty liver patients with grade F2, F3, F4.

Intervention groups
Intervention group: receiving Ellagic acid capsules 200 mg once a day with one glass of water for 60 days (two months) along with a hypocaloric diet with a reduction of 500 kcal of energy. Placebo group: receiving placebo capsules of the same shape and size once a day with one glass of water for 60 days (two months) along with a hypocaloric diet with a reduction of 500 kcal of energy.

Main outcome variables
The amount of hepatic steatosis is measured by elastography at the beginning and end of the study.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180103038199N16**
Registration date: **2023-05-01, 1402/02/11**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-01, 1402/02/11**
Update count: **0**

Registration date
2023-05-01, 1402/02/11

Registrant information

Name
Vahid Reza Askari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3800 2264

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askariv941@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date
2025-04-21, 1404/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the effectiveness of ellagic acid on liver steatosis in patients with non-alcoholic fatty liver disease

Public title
Evaluation of the effectiveness of ellagic acid on patients with non-alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 30-65 years old Body composition index between 25-35 Diagnosis of liver steatosis by two-dimensional elastography (grade 2 and above) Fatty liver patients with grade F0 and F1
Exclusion criteria:
Viral hepatitis (especially hepatitis C) Alcoholic fatty liver or consumption of alcohol Diseases such as Wilson's disease, hemochromatosis, celiac disease, cirrhosis, biliary obstruction and primary biliary cirrhosis Special nutritional conditions such as starvation, fasting, and intravenous feeding Smoker Breastfeeding or pregnancy History of hypersensitivity to pomegranate and its products Diabetes Taking any kind of herbal supplements Fatty liver patients with grade F2, F3, F4
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The blocked randomization method is used. The volume of each block will be four. Then the list of blocks is written and numbers assigned to them, for example (AABB(1)- BBAA(2)- BABA(3)- BAAB(4)), which will be 15 blocks according to the sample size of 60. Then random numbers between 1 and 15 are selected according to the randomization site Randomaization.com and finally, the treatment allocation list is determined based on the random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Using sealed envelopes Due to the use of a placebo similar to the intervention treatment, the investigator and the participants will not be informed of the assigned treatment, and the analyst will also be unaware of the assigned treatment for the two groups. Finally, after analyzing the data, the researcher who prepared the packages will reveal the codes A and B.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Deputy of Research and Technology of the University, Qurashi Building, Next to Hoveyzeh Cinema, University Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2023-03-07, 1401/12/16
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1401.712

Health conditions studied

1

Description of health condition studied
Patients with non-alcoholic fatty liver disease
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Hepatic steatosis
Timepoint
At the beginning of the study and after 2 months of treatment
Method of measurement
Elastography

Secondary outcomes

1

Description
Hepatic fibrosis
Timepoint
At the beginning of the study and after 2 months of

treatment
Method of measurement
Elastography

2

Description
Changes in lipid profile
Timepoint
At the beginning of the study and after 2 months of treatment
Method of measurement
Laboratory kit

3

Description
Fasting blood sugar
Timepoint
At the beginning of the study and after 2 months of treatment
Method of measurement
Laboratory kit

4

Description
Fasting insulin
Timepoint
At the beginning of the study and after 2 months of treatment
Method of measurement
Laboratory kit

5

Description
Uric acid
Timepoint
At the beginning of the study and after 2 months of treatment
Method of measurement
Laboratory kit

6

Description
Serum Creatinine
Timepoint
At the beginning of the study and after 2 months of treatment
Method of measurement
Laboratory kit

7

Description
Changes in Interleukin-6 levels
Timepoint
At the beginning of the study and after 2 months of treatment
Method of measurement
Laboratory kit

8

Description
Changes in hs-CRP serum level
Timepoint
At the beginning of the study and after 2 months of treatment
Method of measurement
Laboratory kit

9

Description
Changes in ALT level
Timepoint
At the beginning of the study and after 2 months of treatment
Method of measurement
Laboratory kit

10

Description
Changes in AST level
Timepoint
At the beginning of the study and after 2 months of treatment
Method of measurement
Laboratory kit

11

Description
Changes in ALP level
Timepoint
At the beginning of the study and after 2 months of treatment
Method of measurement
Laboratory kit

12

Description
Changes in GGT level
Timepoint
At the beginning of the study and after 2 months of treatment
Method of measurement
Laboratory kit

13

Description
Physical activity score
Timepoint
At the beginning of the study and after 1 and 2 months of treatment
Method of measurement
IPAQ questionnaire

14

Description
Body weight

Timepoint
At the beginning of the study and after 1 and 2 months of treatment
Method of measurement
A scale with an accuracy of 100 grams

15

Description
Body Composition
Timepoint
At the beginning of the study and after 1 and 2 months of treatment
Method of measurement
BIA

Intervention groups

1

Description
Intervention group: receiving Ellagic acid capsules 200 mg once a day with one glass of water for 60 days (two months) along with a hypocaloric diet with a reduction of 500 kcal of energy.
Category
Treatment - Drugs

2

Description
Control group: receiving placebo capsules of the same shape and size once a day with one glass of water for 60 days (two months) along with a hypocaloric diet with a reduction of 500 kcal of energy.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinics affiliated to Mashhad University of Medical Sciences
Full name of responsible person
Dr Vahid Reza Askari
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Mashhad University of Medical Science, Azadi Square
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Sponsors / Funding sources

1

Sponsor
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Vahid Reza Askari
Position
Assistant professor of clinical pharmacology
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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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