Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

The effect of supplementation with pomegranate peel extract on liver enzymes, hs-CRP and lipid profile in patients with non-alcoholic fatty liver disease: a randomized, double-blind clinial trial.

Protocol summary

Study aim

effect of supplementation with pomegranate peel extract on liver enzymes, hs-CRP and lipid profile in patients with NAFLD.

Design

A 10-week randomized, double-blinded, parallel clinical trial on 46 patients with NAFLD.

Settings and conduct

Patients are randomly divided into intervention and placebo groups . A written consent form is obtained from the patients. The degree of hepatic steatosis is determined using ultrasound. The 3-day of 24-hour dietary recall is taken at the beginning and end of the study. A diet for weight loss will be given to each patients. Patients' compliance is monitored by telephone every 15 days. Fasting blood samples are taken at the beginning and end of the study. The study protocol has been approved by the ethics committee of Iran University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Liver enzyme(ALT) greater than 20 IU/L for women and greater than 30 IU/L for men. Evidence of fatty liver in ultrasonography with a score of 1 or 2. Being volunteer to attend. age: 30 to 60 years. BMI: 25 to 35. Exclusion criteria: Other acute or chronic hepatic disorders cardiovascular disease, renal disease, infectious disease, diabetes, cancer. hemorrhoid or chronic constipation. intensive weight loss or weight gain during 3 months prior to intervention. Any use of antioxidant supplements or hepatotoxic medications during one month prior to intervention. Use of lipid lowering or insulin-sensitizing medications. Problem in blood coagulation. Dysmenorrhea. excessive bleeding during menses. History of benign tumours. pregnancy. lactation.

Intervention groups

Intervention group: 2 capsules of pomegranate peel extract daily. placebo group: 2 starch capsules daily.

Main outcome variables

Serum levels of ALT and AST are the main outcomes of the study. Other variables include total cholesterol, triglycerides, HDL-C, LDL-C, alkaline phosphatase and hs-CRP.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091114002709N58**
Registration date: **2022-01-11, 1400/10/21**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-11, 1400/10/21**
Update count: **0**

Registration date

2022-01-11, 1400/10/21

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2023-01-05, 1401/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supplementation with pomegranate peel extract on liver enzymes, hs-CRP and lipid profile in patients with non-alcoholic fatty liver disease: a randomized, double-blind clinial trial.

Public title

effect of pomegranate peel extract on non-alcoholic fatty liver disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Alanine aminotransferase (ALT) greater than 20 IU/L for women and greater than 30 IU/L for men. Evidence of fatty liver in ultrasonography with a score of 1 or 2. Being volunteer or Wishing to attend. age: 30 to 60 years. BMI: 25Kg/m2 to 35Kg/m2.

Exclusion criteria:

Other acute or chronic hepatic disorders cardiovascular disease, renal disease, infectious disease, diabetes, cancer. hemorrhoid or chronic constipation. intensive weight loss or weight gain during 3 months prior to intervention. Any use of antioxidant supplements during 1 month prior to intervention. Use of hepatotoxic medications during last month. Use of lipid lowering medications or insulin-sensitizing medications. Problem in blood coagulation. Dysmenorrhea or excessive bleeding during menses. History of benign tumours. Consumption of alcohol, addictive drugs and smoking. The patient's unwillingness to continue cooperation. pregnancy. lactation.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

By random allocation participants will divide into intervention and placebo groups each of which consist of 23 patients. Since The results of biochemical tests varies in age range from 30 to 60 and it can affect the result of the intervention and to make sure about the equal distribution of variables among groups, randomization is done in a randomized, stratified method based on the age. A randomized list is produced and randomization will be done based on the age by relevant list.

Blinding (investigator's opinion)

Double blinded

Blinding description

pomegranate extract capsules and placebo capsules are similar in appearance, weight and packaging. individual codes will be used on the packaging.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway.

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2021-11-21, 1400/08/30

Ethics committee reference number

IR.IUMS.REC.1400.760

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Alanine aminotransferase (ALT)

Timepoint

At the beginning and at the end of week 10

Method of measurement
Laboratory kit

2

Description
Aspartate aminotransferase (AST)
Timepoint
At the beginning and at the end of week 10
Method of measurement
Laboratory kit

Secondary outcomes

1

Description
high density lipoprotein cholesterol (HDL-C)
Timepoint
At the beginning and at the end of week 10
Method of measurement
Laboratory kit

2

Description
Low density lipoprotein cholesterol (LDL-C)
Timepoint
At the beginning and at the end of week 10
Method of measurement
Laboratory kit

3

Description
Alkaline phosphatase (ALP)
Timepoint
At the beginning and at the end of week 10
Method of measurement
Laboratory kit

4

Description
Total cholesterol (TC)
Timepoint
At the beginning and at the end of week 10
Method of measurement
Laboratory kit

5

Description
Triglyceride (TG)
Timepoint
At the beginning and at the end of week 10
Method of measurement
Laboratory kit

6

Description
High sensitive reactive protein (hs-CRP)
Timepoint
At the beginning and at the end of week 10
Method of measurement
Laboratory kit

Intervention groups

1

Description
Intervention group: consumption of two capsules per day (each of them containing 500mg extract of pomegranate peel) for 12 weeks
Category
Treatment - Other

2

Description
Control group: consumption of two placebo capsules for 10 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul akram Hospital
Full name of responsible person
Marjan Mokhtare
Street address
Niayesh St., Sattarkhan Ave., Rasoul akram Hospital.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyyed Abbas Motevallian, deputy head of Research and technology, Iran university of medical sci
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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Farzad Shidfar
Position
Professor
Latest degree
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Person responsible for updating data

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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
There is no further information

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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Information on the main implications can be shared at the end of the study.

When the data will become available and for how long

The access period will be 6 months after the results are published.

To whom data/document is available

The data from this study will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

6 months after the publication of the articles obtained from the data of this project, at the request of the person in charge of the project and his consent, the study data can be made available to researchers.

From where data/document is obtainable

Applicants can contact the responsible author via email or the following mailing address to obtain the required data. Postal address: Tehran-Hemmat Highway-Iran University of Medical Sciences-Faculty of Health-Department of Nutrition. Contact number: 00982188622755. Email: shidfar.f@iums.ac.ir

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

Applicants will be able to access the study data by sending an email to the responsible author within a maximum of one week.

Comments