Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of pomegranate peel dry extract supplementation on lipid profile, inflammatory and oxidative stress factors and nutritional status in patients with non-alcoholic fatty liver: A randomized clinical trial

Protocol summary

Study aim

Determination of the effect of supplementation with dry pomegranate peel extract on lipid profile, inflammatory markers and oxidative stress and nutritional status and hepatic steatosis in patients with NAFLD

Design

This study is a double-blind RCT that investigates the effect of supplementation with dry pomegranate peel extract for eight weeks at daily dose of 1500 (two capsules of 750 mg) on lipid profile, inflammatory markers and oxidative stress and nutritional status and liver fibrosis and steatosis status in NAFLD patients. Study groups: intervention and control (each n = 27).

Settings and conduct

Demographic information and medical history and anthropometric indices, BP and body composition (BIA), three-day food recall and IPAQ will be measured before, between and after the study. 5 cc of blood is taken (before & after the intervention) after 12-hour fasting, to evaluate laboratory indicators. All patients will be given hypocaloric diet. Mediterranean diet recommendations and physical activity will be given. At the end, changes in the status of steatosis and liver fibrosis in patients will be assessed.

Participants/Inclusion and exclusion criteria

Inclusion: 18 to 65 years, diagnosis of hepatic steatosis, filling out the consent form exclusion: pregnancy, lactation, morbidobesity, history of alcohol consumption or hepatotoxic drugs, any immunodeficiency disorder, HIV, liver or kidney failure, other liver diseases, history of FA, bariatric surgery

Intervention groups

Intervention group: lifestyle interventions (diet therapy + PA), supplementation of dry extract of pomegranate peel with 2 capsules each having 750 mg daily for 8 weeks.

Main outcome variables

Assessment of anthropometric indices, body composition, serum concentration of MDA, SOD, GPX, TC, HDL-C, LDL-C, TG, FBS and insulin, ALT, ALP, AST, IL6 and CRP and 3-day food recall, IPAQ and steatosis and hepatic fibrosis status.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210726051988N1**
Registration date: **2021-09-14, 1400/06/23**
Registration timing: **prospective**

Last update: **2021-09-14, 1400/06/23**
Update count: **0**

Registration date

2021-09-14, 1400/06/23

Registrant information

Name

Hanieh Barghchi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3840 4558

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-07, 1400/07/15

Expected recruitment end date

2022-04-20, 1401/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of pomegranate peel dry extract supplementation on lipid profile, inflammatory and oxidative stress factors and nutritional status in patients with non-alcoholic fatty liver: A randomized clinical trial

Public title

Effects of pomegranate peel dry extract supplementation on non-alcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-60 years old Detection of hepatic steatosis by two-dimensional elastography device Filling out the informed consent form by the patient

Exclusion criteria:

Pregnancy and lactation Morbid obesity (BMI > 40) Alcohol consumption history (more than 20 grams per day for women and more than 30 grams per day for men), Having any type of immunodeficiency disorder, including: autoimmune disorders, cancer, human immunodeficiency virus (HIV) Hepatic or renal insufficiency, other liver diseases such as hepatitis, alcoholic fatty liver consumption of hepatotoxic drugs such as sodium valproate History of food allergy to pomegranate and herbal supplements History of bariatric surgery

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

stratified randomization by sealed envelops: Randomization of samples to the intervention or control group is done based on blocks classified according to the degree of disease and sex. In this way, for example: man-grade one, woman-grade one, man-grade two, woman-grade two, man-grade three, woman-grade three, with sealed envelopes. An attempt is made to assign an equal number from each class to the intervention and control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

participants, investigator and data collectors, outcome assessors will be blinded.

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 science

Street address

Nutrition department, Faculty of medicine Mashhad University of Medical Sciences (MUMS), Azadi square, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2021-08-28, 1400/06/06

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.195

Health conditions studied

1

Description of health condition studied

non alcoholic fatty liver- hepatic steatosis and fibrosis- pomegranate peel

ICD-10 code

K76.0

ICD-10 code description

Fatty (Chang of) liver, not elsewhere classified, Nonalcoholic fatty liver disease

Primary outcomes

1

Description

hepatic steatosis and fibrosis

Timepoint

before and at the end of the study

Method of measurement

Two-dimensional elastography device

Secondary outcomes

1

Description
Measurement of anthropometric indices (height, weight, body mass index)
Timepoint
Before, in the middle and at the end of the study
Method of measurement
Scales with an accuracy of 100 grams, meters,

2

Description
Measurement of body composition (percentage of adipose and lean tissue) by BIA device
Timepoint
Before, in the middle and at the end of the study
Method of measurement
BIA

3

Description
Measurement of serum concentrations of oxidative stress indicators including malondialdehyde, superoxide dismutase, glutathione peroxidase,
Timepoint
Before and at the end of the study
Method of measurement
Laboratory methods

4

Description
Evaluation of IPAQ physical activity questionnaire and three-day food recall
Timepoint
Before, in the middle and at the end of the study
Method of measurement
statistical methods

5

Description
Measurement of serum concentrations of lipid profiles including TC, HDL-C, LDL-C and TG,
Timepoint
Before and at the end of the study
Method of measurement
Laboratory methods

6

Description
Measurement of serum concentrations of fasting blood glucose and insulin,
Timepoint
Before and at the end of the study
Method of measurement
Laboratory methods

7

Description
Measurement of serum concentrations of hepatic profiles including ALT, ALP and AST,
Timepoint
Before and at the end of the study
Method of measurement
Laboratory methods

8

Description
Measurement of serum concentrations of inflammatory markers including interleukin 6 and reactive protein C
Timepoint
Before and at the end of the study
Method of measurement
Laboratory methods

Intervention groups

1

Description
In the intervention group, in addition to lifestyle interventions (diet therapy + physical activity), supplementation of dry extract of pomegranate peel with a dose of 1500 mg is performed for 8 weeks. Each capsule containing 750 mg of dry pomegranate peel extract is given daily with two main meals (breakfast and dinner) for 8 weeks.
Category
Treatment - Drugs

2

Description
In the control group, in addition to lifestyle interventions (diet + physical activity), patients received two capsules containing 750 mg placebo every day for 8 weeks with the same characteristics in terms of shape, smell, color, etc., along with two main meals (breakfast and Dinner) for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital Specialized Clinic
Full name of responsible person
Dr. Ladan Goshayeshi, Dr. Mohsen Nematy
Street address
Imam Reza Hospital Specialized Clinic- Imam Reza square- Mashhad- Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
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Mashhad university of medical sciense- Azadi Square- Mashhad- Iran
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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
Hanieh Barghchi
Position
MSc student of clinical nutrition
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

I will inform at the end of the study.

When the data will become available and for how long

I will inform at the end of the study.

To whom data/document is available

I will inform at the end of the study.

Under which criteria data/document could be used

I will inform at the end of the study.

From where data/document is obtainable

I will inform at the end of the study.

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

I will inform at the end of the study.

Comments