

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

The effect of pomegranate extract tablet on some of metabolic factor, hepatokines (fetuin A, FGF21), inflammatory biomarkers, anthropometric indices and grade of fatty liver in patients with non-alcoholic fatty Liver disease

Protocol summary

Study aim

The effect of pomegranate extract tablet on some of metabolic factor, hepatokines (fetuin A, FGF21), inflammatory biomarkers, anthropometric indices and grade of fatty liver in patients with non-alcoholic fatty Liver disease

Design

The present study is a simple randomized clinical trial on 50 subjects with nonalcoholic fatty liver. In this study, individuals are divided into two groups of drugs and placebo. Randomization will done using quadratic block. Statistical software (Minitab) will use to perform randomized block.

Settings and conduct

A double blind randomized clinical trial. Blinding on patients and researchers. 50 Patients with non alcoholic fatty liver into pomegranate extract tabley and placebo groups. The period of intervention:12 weeks.

Participants/Inclusion and exclusion criteria

inclusion criteria: Age 18 to 65 years, Body mass index 29.4 to 40, Presence of non-alcoholic steathepatitis in ultrasonography with degree of steatosis higher than grade 1, Not having a special diet, The liver enzyme concentration greater than 1.5 times the highest normal up to a 5 times more than normal. Exclusion criteria: History of hepatitis, Other liver diseases, Gastrointestinal diseases, Cardiovascular Diseases, Anemia, Hospitalized patients, Kidney diseases, Endocrine disorders, Alcohol drinking, Smoking, Taking any medicine, insulin, hepatic steatosis drugs, Intravenous nutrition, Special diets, Taking vitamin supplements, Pregnancy or breastfeeding, Menopause. Weight loss surgery in the last year.

Intervention groups

Group 1: pomegranate extract tablet; Group 2: placebo

Main outcome variables

Anthropometry indices, liver enzymes, fasting blood sugar; fasting insulin; Insulin resistance; adiponectin; fetuin A; fibroblast growth factor 21; inflammation factors; blood pressure; degree of hepatic steatosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140107016123N14**

Registration date: **2019-12-04, 1398/09/13**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-04, 1398/09/13**

Update count: **0**

Registration date

2019-12-04, 1398/09/13

Registrant information

Name

Sima Jafarirad

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

jafarirad-s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pomegranate extract tablet on some of metabolic factor, hepatokines (fetuin A, FGF21), inflammatory biomarkers, anthropometric indices and grade of fatty liver in patients with non-alcoholic fatty Liver disease

Public title

The effect of pomegranate extract on non alcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age:18 to 65 years old Body mass index 29.4 to 40 Presence of non-alcoholic steathepatitis in ultrasonography with degree of steatosis higher than grade 1 consent with collaboration in study Not taking any dietary supplements Not being on a special diet the liver enzyme serum level (Alanine aminotransferase (ALT) or Aspartate aminotransferase (AST)) 1.5 times greater than the highest normal up to a 5 times more than the highest level of normal range non diabetes

Exclusion criteria:

People with a history of hepatitis including A, B and C; Other liver diseases including autoimmune liver disease, liver transplantation, liver metabolic disease, Wilson's disease gastrointestinal diseases cardiovascular diseases anemia kidney diseases endocrine disorders (such as hypothyroidism or hyperthyroidism, Cushing's) having a history of drinking more than 10 grams per day in women and more than 20 grams per day in men smoking Taking any medicine, insulin, hepatic steatosis drugs getting intravenous nutrition getting special diets and taking vitamin supplements in the last three months pregnancy or lactating menopause weight loss surgery during the last year Unwillingness to cooperate

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The present study is a simple randomized clinical trial on

subjects with nonalcoholic fatty liver. In this study, individuals are divided into two groups of drugs and placebo. Randomization will be done using quadratic block. Statistical software (Minitab) will be used to perform randomized block.

Blinding (investigator's opinion)

Double blinded

Blinding description

To make this study double-blinded and keep the researchers and participants unaware of the taken tablets, before the intervention, the container of pomegranate extract and placebo were coded as A or B by a third person (non-researcher).

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan, Ahvaz, Iran

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ahvaz

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Khouzestan

Postal code

61357-15794

Approval date

2019-10-12, 1398/07/20

Ethics committee reference number

IR.AJUMS.REC.1398.519

Health conditions studied**1****Description of health condition studied**

Nonalcoholic fatty liver disease (NAFLD)

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes**1****Description**

Alanine aminotransferase

Timepoint
before intervention and after 12 weeks
Method of measurement
seum level

2

Description
Aspartate transaminase
Timepoint
before intervention and after 12 weeks
Method of measurement
serum level

3

Description
gamma glutamyl transferase
Timepoint
before intervention and after 12 weeks
Method of measurement
serum level

4

Description
alkaline phosphatase
Timepoint
before intervention and after 12 weeks
Method of measurement
serum level

5

Description
triglycerides
Timepoint
before intervention and after 12 weeks
Method of measurement
serum level

6

Description
total cholesterol
Timepoint
before intervention and after 12 weeks
Method of measurement
serum level

7

Description
Low density lipoprotein (LDL)
Timepoint
before intervention and after 12 weeks
Method of measurement
serum level

8

Description
High density lipoprotein (HDL)
Timepoint

before intervention and after 12 weeks
Method of measurement
serum level

9

Description
fasting blood sugar
Timepoint
before intervention and after 12 weeks
Method of measurement
serum level

10

Description
fasting insulin
Timepoint
before intervention and after 12 weeks
Method of measurement
serum level

11

Description
insulin resistance
Timepoint
before intervention and after 12 weeks
Method of measurement
 $405 \div (\text{insulin} \times \text{glucose}) = \text{HOMA-IR}$; Homeostatic model assessment

12

Description
Adiponectin
Timepoint
before intervention and after 12 weeks
Method of measurement
serum level

13

Description
Fetuin A
Timepoint
before intervention and after 12 weeks
Method of measurement
serum level

14

Description
fibroblast growth factor 21(FGF 21)
Timepoint
before intervention and after 12 weeks
Method of measurement
serum level

15

Description
total antioxidant capacity
Timepoint

before intervention and after 12 weeks
Method of measurement
serum level

16

Description
high sensitive C reactive protein (hs-CRP)
Timepoint
before intervention and after 12 weeks
Method of measurement
serum level

17

Description
interlukin-6(IL-6)
Timepoint
before intervention and after 12 weeks
Method of measurement
serum level

18

Description
weight
Timepoint
before intervention and after 12 weeks
Method of measurement
scale

19

Description
waist circumference
Timepoint
before intervention and after 12 weeks
Method of measurement
waist circumference in CM

20

Description
body mass index (BMI)
Timepoint
before intervention and after 12 weeks
Method of measurement
Ratio of weight (kg) to second power (in meters)

21

Description
Degree of hepatic steatosis
Timepoint
before intervention and after 12 weeks
Method of measurement
sonography

Secondary outcomes

1

Description

systolic blood pressure
Timepoint
before intervention and after 12 weeks
Method of measurement
Blood pressure monitor

2

Description
diastolic blood pressure
Timepoint
before intervention and after 12 weeks
Method of measurement
Blood pressure monitor

Intervention groups

1

Description
Intervention group: Pomegranate extract tablet 225 mg twice daily for 12 weeks
Category
Treatment - Other

2

Description
Control group: Placebo twice daily for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Khomieni Hospital
Full name of responsible person
Sima Jafarirad
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Sima Jafarirad

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Sima Jafarirad

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Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Reza Goodarzi

Position

Ph.D. condidate

Latest degree

Master

Other areas of specialty/work

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goodarzi121@yahoo.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