Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 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 nonalcholic 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)

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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 nonalcholic 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.
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÷(insulin×glucose)=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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1

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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
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Sima Jafarirad
Position
Associate Professor
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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