

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparing the effects of pomegranate and orange juice on serum total antioxidant capacity, MDA, TNF- α , ALT and AST enzymes, lipoproteins, insulin resistance and metabolic syndrome indices in non- alcoholic fatty liver patients

Protocol summary

Summary

Main objective of this study is to compare the effects of pomegranate and orange juice on serum total antioxidant capacity , MDA, TNF- α , ALT and AST enzymes, lipoproteins , insulin resistance and metabolic syndrome indices in non- alcoholic fatty liver patients. In this clinical trial, men and women (n=70), aged 30-65 years old who referred to clinics of Tehran university of medical sciences will be randomly assigned into pomegranate or orange juice for 12 weeks. All the patients in both groups will receive a hypo caloric diet for 90 days according to their weight, age and sex. Two servings of their daily fruit intakes will be substituted by one glass of either pomegranate or orange juice in their regular diet. 24 hour dietary recall, food frequency questionnaire and international physical activity questionnaire will be completed at the beginning of the study and the end of each month. Anthropometric indices, serum lipids and lipoproteins profile, fasting glucose, AST and ALT enzymes, serum total antioxidant capacity , MDA, TNF- α , insulin resistance and metabolic syndrome indices will be determined at the baseline and after 12 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102232709N17**

Registration date: **2011-03-11, 1389/12/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-03-11, 1389/12/20

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research, Tehran University of Medical Sciences, Gastrointestinal & Liver Disease Research Center (Firoozgar GILDRC)

Expected recruitment start date

2011-04-04, 1390/01/15

Expected recruitment end date

2011-06-05, 1390/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of pomegranate and orange juice on serum total antioxidant capacity, MDA, TNF- α , ALT and AST enzymes, lipoproteins, insulin resistance and metabolic syndrome indices in non- alcoholic fatty liver patients

Public title

Comparing the effects of pomegranate and orange juice in non-alcoholic fatty liver disease patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: signing written informed consent, age between 30 and 65, diagnosis of non-alcoholic fatty liver disease by fatty infiltration on ultrasound and abnormal serum liver function tests (AST or ALT>30 u/l in men and >20 in women), no smoking, BMI≥ 25, no pregnancy or lactation, no use of dietary supplements one month prior to enrollment, not having diabetes, renal impairment, acute heart disease, thyroid disease, other form of liver disease (viral or autoimmune hepatitis, metabolic and hereditary liver disease) and any diseases that can affect on body weight, not having severe gaining or losing weight diet in the 3 month prior to the enrollment, no use of medication that could affect body weight in the 3 month prior to the enrollment, no use of drugs that induces steatosis (amidarone, methotrexate, systemic glucocorticoid, tetracycline, tamoxifen, estrogen, anabolic steroids, valporic acid) Exclusion Criteria: those who are not interested in participating in the study, pharmacological treatment with some potential treatment, any diseases which need special treatment, pregnancy during the study period

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Faculty of Public Health of Tehran University of
Medical Sciences

Street address

Number 60, Alvand street, Argentina square, Tehran

City

Tehran

Postal code

1516846515

Approval date

2010-10-10, 1389/07/18

Ethics committee reference number

2402

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

non-alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description**Primary outcomes****1****Description**

AST enzyme

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

enzymatic colorimetry kit

2**Description**

ALT enzyme

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

enzymatic colorimetry kit

3**Description**

hepatic fat infiltration status

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

ultrasound

Secondary outcomes**1****Description**

MDA

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

colorimetry kit

2

Description

TNF- α

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

ELISA

3

Description

total antioxidant capacity

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

colorimetry kit

4

Description

fasting Insulin Level

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

ELISA

5

Description

fasting blood sugar

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

enzymatic colorimetry kit

6

Description

HOMA-R

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

Calculating

7

Description

LDL-C

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

immunoturbidimetry

8

Description

HDL-C

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

immunoturbidimetry

9

Description

triglyceride

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

colorimetry

10

Description

total cholesterol

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

colorimetry

11

Description

blood pressure

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

sphygmomanometer

Intervention groups

1

Description

250 ml/day pomegranate juice for 12 weeks

Category

Other

2

Description

250ml/day orange juice for 12 weeks

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Honor Rasool Akram therapeutic educational center

Full name of responsible person

Dr Shahram Agah

Street address

Sttar khan - Niyayesh street

City

Tehran

2

Recruitment center

Name of recruitment center

Gastrointestinal & Liver Disease Research Center

Full name of responsible person

Dr Merat
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor for Research, Tehran University of
Medical Sciences
Full name of responsible person
Dr Seyyed Abbas Motevalian
Street address
Keshavarz Bld - intersection of Qods street
City
Tehran
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Vice-chancellor for Research, Tehran University of
Medical Sciences
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

2

Sponsor

Name of organization / entity
Gastrointestinal & Liver Disease Research Center
(Firoozgar GILDRC)
Full name of responsible person
Dr Shahram Agah
Street address
Valiasr square - Behafarin street
City
Tehran
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Gastrointestinal & Liver Disease Research Center
(Firoozgar GILDRC)
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin

empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty