Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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
fastinf 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 colestrol
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

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Professor /nutrition PhD
Other areas of specialty/work
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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