Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effects of natural and commercial orange juice consumption in blood pressure and inflammatory factors in healthy volunteers

Protocol summary

Summary

In this randomized cross-over study in healthy volunteers, 30 healthy subjects aged 19–59 years will be selected. The purpose of this study, is to investigate the effect of natural and commercial orange juice consumption on pro-inflammatory cytokines, lipid profile levels, flow-mediated dilatation (FMD) and Blood pressure (BP) in healthy volunteers. Individuals with a history of diabetes; cardiovascular disease; liver and kidney disease as well as those with thyroid disease; pregnant and breastfeeding; individuals with dyslipidemia, metabolic and endocrine diseases and those with a vegetarian diet will be exclude. FMD measurement will done using high-frequency ultrasonography of the brachial artery, blood pressure gauge using a sphygmomanometer and the inflammatory markers (hs-CRP-ICAM-VCAM-IL-6-E-Selecti) and lipid profile levels will be measured using ELISA kits. Participants are randomly divided into two groups . And will consume 500mL orange juice(natural or commercial orange juice); twice a day with breakfast and dinner for 4 weeks, at the beginning and end of a 4-week period, above mentioned factors will be measured. And after a 2wk wash out (no consumption of oranges or orange juice) Groups will be changed and factors will be measured again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205079662N2**
Registration date: **2012-06-10, 1391/03/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-06-10, 1391/03/21

Registrant information

Name
Sedigheh Asgary

Name of organization / entity
Isfahan Cardiovascular Research Center ,Isfahan Cardiovascular Research institute , Physiology Re

Country
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Recruitment status
Recruitment complete

Funding source
Isfahan University of Medical Sciences

Expected recruitment start date
2012-02-20, 1390/12/01

Expected recruitment end date
2012-12-21, 1391/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of natural and commercial orange juice consumption in blood pressure and inflammatory factors in healthy volunteers

Public title
Effects of natural and commercial orange juice consumption in inflammatory factors (hs-CRP; ICAM; VCAM; IL-6; E-Selectin)and endothelial function evaluation (FMD) in healthy volunteers

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Healthy individuals 19-59 years.
Exclusion criteria: Individuals with a history of diseases; diabetes; cardiovascular disease; liver and kidney as well as those with thyroid disease; pregnant and breastfeeding; individuals with dyslipidemia, metabolic and endocrine diseases and those with a vegetarian diet.

Age

From **19 years** old to **59 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hezar jirib st.

City

Isfahan

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

288028

Health conditions studied

1

Description of health condition studied

Blood pressure

ICD-10 code

I10-I15

ICD-10 code description

Hypertensive diseases

2

Description of health condition studied

flow-mediated dilatation (FMD)

ICD-10 code

I70-I79

ICD-10 code description

Diseases of arteries, arterioles and capillaries

Primary outcomes

1

Description

Positive changes in inflammatory markers

Timepoint

Baseline and after 4 weeks

Method of measurement

ELISA kit

2

Description

Positive changes in endothelial function

Timepoint

Baseline and after 4 weeks

Method of measurement

Doppler ultrasonography

Secondary outcomes

1

Description

Decrease in blood pressure

Timepoint

Baseline and after 4 weeks

Method of measurement

Sphygmomanometer

2

Description

Positive changes in lipid profiles

Timepoint

Baseline and after 4 weeks

Method of measurement

kit

3

Description

Cholesterol Level

Timepoint

Before and after 4 weeks

Method of measurement

KIT

4

Description

HDL Level

Timepoint

Before and after 4 weeks
Method of measurement
KIT

5

Description
LDL level
Timepoint
Before and after 4 weeks
Method of measurement
KIT

Intervention groups

1

Description
500 ml of fresh orange juice consumption in group 1 for 4wk
Category
Other

2

Description
500 ml of Commercial orange juice consumption in group 1, for 4wk.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sedigheh tahere Cardiovascular Research Center
Full name of responsible person
mahtab keshvari
Street address
Khorram Street, Jomhori Square
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr.gholam hossin sadri
Street address
Hezar jirib St.
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Sciences
Proportion provided by this source
100
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfahan Cardiovascular Research Center, Applied Physiology Research Center, Isfahan University of M
Full name of responsible person
Sedigheh Asgary
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Pharmacist and PhD Pharmacogenetics
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Person responsible for updating data

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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