

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of citrus aurantium and citrus aurantifolia on endothelial function among overweight children and adolescents aged 9-18

Protocol summary

Summary

In this triple-blind clinical trial, 90 overweight or obese children and adolescents aged 9-18 years are randomly selected. Written informed consent will be obtained from parents. Inclusion criteria include age (9-18 years), and body mass index (BMI) above 85th centile for age and sex. Hypothyroidism, medical therapy for dyslipidemia, smoking or exposure to tobacco are considered as exclusion criteria. Demographic and anthropometric characteristics including age, sex, weight, height and BMI will be recorded. Lipid profile and flow-mediated dilation (FMD) showing endothelial dysfunction will be measured at baseline and end of the study. Participants will randomly assigned to three groups (each group includes 30 subjects), receiving citrus aurantium or citrus aurantifolia extracts or placebo (corn starch) capsules (1 capsule/12 hour), respectively. The study will last for one month. Statistical analysis will be conducted using SPSS version 20, Paired t-test, Analysis of Variance (ANOVA), and Post-hoc analysis will be used to test significant differences between study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102715190N1**

Registration date: **2013-12-07, 1392/09/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-07, 1392/09/16

Registrant information

Name

Elham Khosravi Bakhtiari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1433 4332

Email address

elham_khosravi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2013-11-17, 1392/08/26

Expected recruitment end date

2014-02-19, 1392/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of citrus aurantium and citrus aurantifolia on endothelial function among overweight children and adolescents aged 9-18

Public title

Effect of citrus aurantium and citrus aurantifolia on endothelial function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age (9-18 years); body mass index (BMI) above 85th centile for age and sex; no hypothyroidism. Exclusion criteria: medical therapy for dyslipidemia; smoking or exposure to tobacco.

Age

From **9 years** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
In this triple-masked study, participant, the project manager and statistician are not aware of randomly allocation of subjects to intervention and control groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Hezar Jarib St.

City
Isfahan

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
392115

Health conditions studied

1

Description of health condition studied
overweight and obesity

ICD-10 code
E65-E68

ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
flow-mediated dilation (FMD)

Timepoint
baseline and at the end of the study (after 1 month intervention)

Method of measurement
high-resolution B-mode sonography

Secondary outcomes

empty

Intervention groups

1

Description
placebo (corn starch) as similar appearance capsules (1 capsule/12 hour) for control group

Category
Treatment - Drugs

2

Description
citrus aurantium capsules (1 capsule/12 hour) for intervention group 1

Category
Treatment - Drugs

3

Description
citrus aurantifolia capsules (1 capsule/12 hour) for intervention group 2

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Child Growth and Development Research Center

Full name of responsible person
Elham Khosravi

Street address
No 26, Ghaem blind-alley, Asiyab alley, Kaveh St.

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person
Dr.Peyman Adibi

Street address
Hezar jarib St. Vice chancellor for research, Isfahan University of Medical Sciences

City
Isfahan

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, 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

Name of organization / entity
Isfahan University of Medical Sciences

Full name of responsible person
Elham Khosravi

Position
Resident of cardiovascular diseases

Other areas of specialty/work

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Person responsible for scientific inquiries

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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