

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Parallel randomized clinical trial on the effects of citrus aurantifolia extract on components of metabolic syndrome and markers of endothelial dysfunction among overweight children and adolescents aged 9-18

Protocol summary

Summary

In this triple-masked parallel randomized clinical trial, which will assess the effect of citrus aurantifolia extract on components of metabolic syndrome and markers of endothelial dysfunction, 60 overweight or obese children and adolescents (9-18 years), referring from schools and health centers to child growth and development research center, 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, waist circumference (WC), and BMI will be recorded. Lipid profile, fasting blood glucose (FBS), blood pressure, intercellular adhesion molecule (ICAM), vascular cell adhesion molecule (VCAM) showing endothelial function will be measured at baseline and end of the study. Participants will randomly assigned to two groups (each group includes 30 subjects), receiving citrus aurantifolia extract (intervention group) or placebo; corn starch (control group) as 3 capsule/day, respectively. The study will last for one month. Statistical analysis will be conducted using SPSS version 16, 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: **IRCT201311231434N11**
Registration date: **2014-01-01, 1392/10/11**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-01, 1392/10/11

Registrant information

Name

Roya Kelishadi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

kelishadi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2013-11-23, 1392/09/02

Expected recruitment end date

2014-02-21, 1392/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Parallel randomized clinical trial on the effects of citrus aurantifolia extract on components of metabolic syndrome and markers of endothelial dysfunction among overweight children and adolescents aged 9-18

Public title

Parallel randomized clinical trial on the effects of citrus aurantifolia extract on components of metabolic syndrome and markers of endothelial dysfunction among overweight children and adolescents aged 9-18

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age (9-18 years); and body mass index (BMI) above 85th centile for age and sex. Exclusion criteria: Hypothyroidism; 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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib St., Isfahan

City

Isfahan

Postal code

73461-8174

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

392352

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

body mass index

Timepoint

baseline and at the end of study

Method of measurement

measurment

Secondary outcomes

1

Description

serum triglyceride

Timepoint

baseline and at the end of study (after one month)

Method of measurement

labaratory

2

Description

total cholesterol

Timepoint

baseline and at the end of study (after one month)

Method of measurement

labaratory

3

Description

high-density lipoprotein

Timepoint

baseline and at the end of study (after one month)

Method of measurement

labaratory

4

Description

Low-density lipoprotein

Timepoint

baseline and at the end of study (after one month)

Method of measurement

labaratory

5

Description

fasting blood glucose

Timepoint

baseline and at the end of study (after one month)
Method of measurement
laboratory

6

Description
waist circumference
Timepoint
baseline and at the end of study (after one month)
Method of measurement
elastic tape

7

Description
blood pressure
Timepoint
baseline and at the end of study (after one month)
Method of measurement
barometer

8

Description
intercellular adhesion molecule (ICAM)
Timepoint
baseline and at the end of study (after one month)
Method of measurement
laboratory

9

Description
vascular cell adhesion molecule (VCAM)
Timepoint
baseline and at the end of study (after one month)
Method of measurement
laboratory

Intervention groups

1

Description
citrus aurantifolia extract (3 capsule/day) for intervention group
Category
Treatment - Drugs

2

Description
placebo (corn starch) (3 capsule/day) for control group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

child growth and development research center
Full name of responsible person
Dr.Maryam Kargar
Street address
Isfahan University of Medical Sciences, Hezar Jarib St.,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr.Peyman Adibi
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Vice chancellor for research, Isfahan University of
Medical Sciences, Hezar Jarib St., Isfahan
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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
Name of organization / entity
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Isfahan University of Medical Sciences

Full name of responsible person

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Position

Professor, Specialist of pediatrics

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Web page address**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