Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Parallel randomized clinical trial on the effects of citrus aurantium 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 perform to assess the effect of citrus aurantium extract on components of metabolic syndrome and markers of endothelial function, 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 aurantium 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: **IRCT201311201434N10**
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

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-02-20, 1392/12/01

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 aurantium 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 aurantium 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
392350

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
fasting blood glucose
Timepoint
baseline and at the end of study (after one month)
Method of measurement
labaratory

2

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

3

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

4

Description
serum triglyceride
Timepoint
baseline and at the end of study (after one month)
Method of measurement
labaratory

5

Description
total cholesterol
Timepoint

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

6

Description
Low-density lipoprotein
Timepoint
baseline and at the end of study (after one month)
Method of measurement
labaratory

7

Description
high-density lipoprotein
Timepoint
baseline and at the end of study (after one month)
Method of measurement
labaratory

8

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

9

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

Intervention groups

1

Description
citrus aurantium 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.Mehrnaz Moini
Street address
Isfahan University of Medical Sciences, Hezar Jarib St., Isfahan
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
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
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
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resident of pediatrics
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Person responsible for scientific inquiries

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professor, specialist of pediatrics

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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