# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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**
+98 31 1792 3060
**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**
labaratory

**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**
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 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., Isfahan
**City**
Isfahan

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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
**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**
**Name of organization / entity**
Isfahan University of Medical Sciences
**Full name of responsible person**
Dr.Maryam Kargar
**Position**
resident of pediatrics
**Other areas of specialty/work**
**Street address**
Isfahan University of Medical Sciences, Hezar Jarib St., Isfahan
**City**
Isfahan
**Postal code**
73461-8174
**Phone**
+98 31 1387 6006
**Fax**

**Email**
Maryam kargar9 @ yahoo.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Isfahan University of Medical Sciences
**Full name of responsible person**
Dr.Roya Kelishadi
**Position**
Professor, Specialist of pediatrics
**Other areas of specialty/work**
**Street address**
Isfahan University of Medical Sciences, Hezar Jarib St., Isfahan
**City**
Isfahan
**Postal code**
73461-8174
**Phone**
+98 31 1387 6006
**Fax**
**Email**
kelishadi@med.mui.ac.ir
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Isfahan University of Medical Sciences
**Full name of responsible person**
Dr.Maryam Kargar
**Position**
resident of pediatrics
**Other areas of specialty/work**
**Street address**
Isfahan University of Medical Sciences, Hezar Jarib St., Isfahan
**City**
Isfahan
**Postal code**
73461-8174
**Phone**
+98 31 1387 6006
**Fax**
**Email**
Maryam kargar9 @ yahoo.com
**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*