

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 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

###### 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

2013-11-22, 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**

laboratory

**6**

**Description**

Low-density lipoprotein

**Timepoint**

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

**Method of measurement**

laboratory

**7**

**Description**

high-density lipoprotein

**Timepoint**

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

**Method of measurement**

laboratory

**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 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

**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**

Dr.Mehrnaz Moini

**Position**

resident of pediatrics

**Other areas of specialty/work**

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## 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**

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## Person responsible for updating data

### Contact

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Isfahan University of Medical Sciences

**Full name of responsible person**

Dr.Mehrnaz Moini

**Position**

resident of pediatrics

**Other areas of specialty/work**

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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*