

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jul 2026

### The effect of low glycemic index diet on childhood obesity

#### Protocol summary

##### Summary

The objective is to study the effects of low glycemic index diet on inflammatory factors, adiponectin, lipid profile and apolipoproteins in obese and overweight girls. Obese or overweight girls who have catamenia and their ages are less than 18 years are included in this study. The subjects not following the research protocols will be excluded. The requirement sample size is 36 subjects. This parallel study will be conducted in 10 weeks. Low glycemic index diet is administered to intervention group and nutritional healthy guidelines are administered to non-intervention group. At the end of the study, anthropometric variables, blood pressure, inflammatory factors, adiponectin and lipid profile will be evaluated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201109272839N4**

Registration date: **2011-11-08, 1390/08/17**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-11-08, 1390/08/17

##### Registrant information

###### Name

Leila Azadbakht

###### Name of organization / entity

Nutrition department, School of health, Isfahan University of Medical Sciences, Isfahan, Iran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1792 2719

###### Email address

azadbakht@hlth.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2011-09-01, 1390/06/10

##### Expected recruitment end date

2011-11-21, 1390/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of low glycemic index diet on childhood obesity

##### Public title

The effect of low glycemic diet on metabolic status and inflammation in obese girls

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: being girl; being in pubertal age; less than 18 years old; being in >85th percentile of WHO's body mass index; Not incidence of chronic or acute diseases; not consuming confounding medications  
exclusion criteria: low compliance to administrated diet; Incidence of chronic or acute diseases; Beginning to consume confounding medications; Not following the research protocol

##### Age

From **13 years** old to **18 years** old

##### Gender

Female

##### Phase

N/A

##### Groups that have been masked

No information

## Sample size

Target sample size: 36

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethical Committee Of Esfahan University Of Medical  
Scie

##### Street address

Esfahan university of medical science

##### City

Esfahan

##### Postal code

#### Approval date

2011-10-01, 1390/07/09

#### Ethics committee reference number

390246

## Health conditions studied

### 1

#### Description of health condition studied

overweight and obesity

#### ICD-10 code

E66.0

#### ICD-10 code description

Obesity due to excess calories

## Primary outcomes

### 1

#### Description

low glycemic index diet

#### Timepoint

in 2nd, 4th, 6th, 8th and 10th weeks

#### Method of measurement

dietary record

## Secondary outcomes

### 1

#### Description

bmi, weight, height, waist circumference, SBP, DBP

#### Timepoint

At the beginning of the study and 2th, 4th, 6th, 8th, 10th  
weeks

#### Method of measurement

barometer, digital scales, meter

### 2

#### Description

adiponectine, CRP, IL-6

#### Timepoint

baseline and at the end of the study

#### Method of measurement

biochemical test

### 3

#### Description

HDL, LDL, FBS, TG, TC

#### Timepoint

baseline and at the end of the study

#### Method of measurement

biochemical test

### 4

#### Description

Apo A, Apo B100, insulin, lip a

#### Timepoint

baseline and at the end of the study

#### Method of measurement

biochemical test

## Intervention groups

### 1

#### Description

intervention group: low glycemic index diet duration:  
10 weeks

#### Category

Lifestyle

### 2

#### Description

non-intervention group: healthy dietary guidelines  
duration: 10 weeks

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Isfahan medical university

##### Full name of responsible person

**Street address****City**

Isfahan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Isfahan medical university

**Full name of responsible person**

Leila Azadbakht

**Street address**

Isfahan medical university, Azadi square, 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 medical university

**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 medical university

**Full name of responsible person**

Sayyed Mohammad Hossein Rouhani

**Position**

Msc student

**Other areas of specialty/work****Street address**

department of public nutrition, School of Nutrition and Food Science, Isfahan University of Medical Sciences

**City**

Hsfahan

**Postal code****Phone**

+98 913 327 6157

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s\_m\_rouhani2003@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Isfahan medical university

**Full name of responsible person**

Leila Azadbakht

**Position**

Associate Professor

**Other areas of specialty/work****Street address**

Department of Community Nutrition, School of Nutrition and Food Science, Isfahan University of Medical Sciences

**City**

Isfahan

**Postal code****Phone**

+98 31 1792 2719

**Fax****Email**

azadbakht@hlth.mui.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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**City**

Isfahan

**Postal code****Phone****Fax****Email****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*