Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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 Commitee Of Esfahan Univercity Of Medical Scie
Street address
Esfahan univercity 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 indexdiet
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 begining 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 indx diet duration: 10weeks
Category
Lifestyle

2

Description
non-intervention group: healthy dietary guidelines duration: 10weeks
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
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Full name of responsible person
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Person responsible for updating data

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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