

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of high protein diet on inflammatory markers and cvd risk factors in overweight and obese children

Protocol summary

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Summary

Effect of high protein diet on anthropometric measurements, cardiovascular disease risk factors and inflammatory markers among overweight and obese children was assessed. Obese or overweight girls and boys with ages of 6-11 years were included in this study. The subjects not following the research protocols will be excluded. The requirement sample size is 50 subjects. This parallel study will be conducted in 10 weeks. High protein diet is administered to intervention group and control diet are administered to non-intervention group. At the end of the study, anthropometric variables, blood pressure, adiponectin and lipid profile will be evaluated.

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2012-05-01, 1391/02/12

Expected recruitment end date

2012-09-01, 1391/06/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307232839N6**

Registration date: **2013-09-07, 1392/06/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-07, 1392/06/16

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

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Email address

Scientific title

Effect of high protein diet on inflammatory markers and cvd risk factors in overweight and obese children

Public title

Effect of high protein on cvd risk factors and inflammation in obese children

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: if they had not known kidney, liver, cardiovascular, allergy, respiratory, thyroid diseases and diabetes; did not taken medications. exclusion criteria: if they did not followed their prescribed diet; had hypercholesterolemia and hypertension.

Age

From **6 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

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 Sciences

City

Esfahan

Postal code**Approval date**

2012-01-03, 1390/10/13

Ethics committee reference number

190169

Health conditions studied**1****Description of health condition studied**

overweight and obesity

ICD-10 code

e66.0

ICD-10 code description

ovweight and obesity in children

Primary outcomes**1****Description**

Aiponectin

Timepoint

week 0 and 10

Method of measurement

biochemical tests

2**Description**

hs-CRP

Timepoint

week 0 and 10

Method of measurement

biochemical tests

3**Description**

tumor necrosis factor alpha

Timepoint

week 0 and 10

Method of measurement

biochemical tests

4**Description**

interlukine 6

Timepoint

week 0 and 10

Method of measurement

biochemical tests

Secondary outcomes**1****Description**

anthropometric measurements

Timepoint

week 0 and 10

Method of measurement

meter, scale

2**Description**

LDL cholesterol

Timepoint

week 0 and 10

Method of measurement

biochemical tets

3**Description**

HDL cholesterol

Timepoint

week 0 and 10

Method of measurement

biochemical tets

4**Description**

total cholesterol

Timepoint

week 0 and 10

Method of measurement

biochemical tets

5

Description

triglyceride

Timepoint

week 0 and 10

Method of measurement

biochemical tests

6

Description

Fasting blood glucose

Timepoint

week 0 and 10

Method of measurement

biochemical tests

7

Description

blood pressure

Timepoint

week 0 and 10

Method of measurement

kaff

8

Description

fasting blood insulin

Timepoint

week 0 and 10

Method of measurement

biochemical tests

Intervention groups

1

Description

intervention: high protein diet

Category

Lifestyle

2

Description

control: standard protein diet

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

clinics of pediatrics

Full name of responsible person

Street address

City

Esfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Leila Azadbakht

Street address

Hezar Jarib street, Azadi square, Esfahan University of Medical Sciences, School of Nutrition and Food Sciences

City

Esfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Vajihe Izadi

Position

MSc

Other areas of specialty/work

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inquiries

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Leila Azadbakht

Position

Associate Professor

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Leila Azadbakht

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Other areas of specialty/work

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Fax

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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