Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 2026

Effect of whole grain consumption or usual dietary recommendation on serum levels of inflammatory bio markers in obese children: a randomized controlled trial

Protocol summary

Summary

Design: cross-over clinical trial. Participants: obese girls aged 8-15 years that were recruited from a private clinic of a pediatrician. The objective: Evaluation the impact of whole-grain consumption on serum levels of adipocytokines and inflammatory bio markers in obese children. Exclusion criteria: history of chronic diseases such as cardiovascular disease (CVD), medication and supplementation use. Setting and conduct: After a 2 week run-in period, participants will be randomly assigned to whole-grain and recommendation group each for 6 weeks. After the first phase of intervention, a 4-week washout period will be applied. Then the participants will be crossed over to the alternate group for additional 6 weeks. To assess the compliance of the participants, we will assess dietary intakes of subjects by the use of dietary records once in every two weeks. Physical activity levels will also be assessed by a physical activity record once in every two weeks. Anthropometric measurements and biochemical assessments including fasting plasma glucose, triglyceride, total-cholesterol, high density lipoprotein cholesterol (HDL-c)-, and low density lipoprotein cholesterol (LDL-c), high sensitivity C-Reactive Protein (hs-CRP), serum amyloid A (SAA), serum inter-cellular adhesion molecule (sICAM-1), serum vascular cell adhesion molecule (sVCAM-1), leptin levels will be measured at the beginning and end of each phases. Appropriate statistical methods will be applied for data analyses. Interventions: usual dietary recommendation includes healthy food choices. First the individual energy requirements will be calculated. The target macro nutrient composition for all participants will be 53% of energy as carbohydrate, 30% of energy as fat and 17% of energy as protein. Subjects will be asked to obtain 50% of their grain servings from whole grain foods each day.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305191485N10**
Registration date: **2013-06-24, 1392/04/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-06-24, 1392/04/03

Registrant information

Name

Ahmad Esmaillzadeh

Name of organization / entity

Department of Nutrition, School of Public Health, Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2012-07-01, 1391/04/11

Expected recruitment end date

2012-09-01, 1391/06/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of whole grain consumption or usual dietary recommendation on serum levels of inflammatory bio markers in obese children: a randomized controlled trial

Public title

Effect of whole grain consumption on inflammation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: female; aged 8-15 years; body mass index greater than 85th percentile for age and sex; lack of adherence to a specific diet and the use of medications and supplements and no history of chronic diseases. Exclusion criteria: history of chronic diseases; the use of medications and supplements such as multivitamin mineral supplementation, omega-3 fatty acids, Aspirin, etc in the past 6 months, hormone therapy and alterations in physical activity

Age

From **8 years** old to **15 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Simple randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib Avenue

City

Isfahan

Postal code

Approval date

2012-06-10, 1391/03/21

Ethics committee reference number

191044

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

serum high sensitive-C Reactive Protein (hs-CRP) levels

Timepoint

Week 2, Week 8, Week 12, Week 18

Method of measurement

high sensitive immunoturbidimetry, mg/dL

2

Description

Serum Amyloid A (SAA) levels

Timepoint

Week 2, Week 8, Week 12, Week 18

Method of measurement

Enzyme-Linked Immunosorbent Assay (ELISA) ،mg/dL

3

Description

serum Inter-Cellular Adhesion Molecule 1 (sICAM-1) levels

Timepoint

Week 2, Week 8, Week 12, Week 18

Method of measurement

Enzyme-Linked Immunosorbent Assay (ELISA) ،µg/L

4

Description

serum vascular cell adhesion molecule 1 (sVCAM-1) levels

Timepoint

Week 2, Week 8, Week 12, Week 18

Method of measurement

Enzyme-Linked Immunosorbent Assay (ELISA) ،µg/L

5

Description

serum leptin levels

Timepoint
Week 2, Week 8, Week 12, Week 18
Method of measurement
Enzyme-Linked Immunosorbent Assay (ELISA) ،ng/mL

Secondary outcomes

1

Description
weight
Timepoint
Baseline, Week 2, Week 8, Week 12, Week 18
Method of measurement
scale, kilogram

2

Description
Waist circumference
Timepoint
Baseline, Week 2, Week 8, Week 12, Week 18
Method of measurement
meter, centimeter

3

Description
hip circumference
Timepoint
Baseline, Week 2, Week 8, Week 12, Week 18
Method of measurement
meter, centimeter

4

Description
body mass index
Timepoint
Baseline, Week 2, Week 8, Week 12, Week 18
Method of measurement
kg/m2, Weight/Height square

5

Description
systolic blood pressure
Timepoint
Baseline, Week 2, Week 8, Week 12, Week 18
Method of measurement
mmHg, digital sphygmomanometer

6

Description
diastolic blood pressure
Timepoint
Baseline, Week 2, Week 8, Week 12, Week 18
Method of measurement
mmHg, digital sphygmomanometer

7

Description
fasting blood sugar
Timepoint
Week 2, Week 8, Week 12, Week 18
Method of measurement
mg/dL, Colorimetric

8

Description
serum Triglyceride levels
Timepoint
Week 2, Week 8, Week 12, Week 18
Method of measurement
photometrics, mg/dL

9

Description
serum total cholesterol levels
Timepoint
Week 2, Week 8, Week 12, Week 18
Method of measurement
photometrics, mg/dL

10

Description
serum Low-Density Lipoprotein cholesterol (LDL-c) levels
Timepoint
Week 2, Week 8, Week 12, Week 18
Method of measurement
Enzymatic, mg/dL

11

Description
serum High-Density Lipoprotein cholesterol (HDL-c) levels
Timepoint
Week 2, Week 8, Week 12, Week 18
Method of measurement
photometrics, mg/dL

Intervention groups

1

Description
whole-grain group:The individual energy requirements will be calculated based on recommendations of the Institute of medicine. The target macro nutrient composition for all participants will be 53% of energy as carbohydrate, 30% of energy as fat and 17% of energy as protein. Subjects in intervention group will be given a list of whole grain foods and will be asked to obtain 50% of their grain servings from whole grain foods each day
Category
Treatment - Other

2

Description
Recommendation group: information about healthy diet has been prescribed for this group.Subjects in the non intervention group also were given a list of whole grain foods and will be asked not to consume any of those foods during this period of study.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
private clinic of a pediatrician

Full name of responsible person
Mahin Hashemipor

Street address
Isfahan University of Medical Sciences, Hezar Jerib Avenue

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
Payman Adibi

Street address
Isfahan University of Medical Sciences, Hezar Jerib Avenue

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
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Full name of responsible person
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Associate Professor

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Person responsible for scientific inquiries

Contact

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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