

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 Esmailzadeh

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

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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

Department of Community Nutrition, School of Nutrition and Food Science, Isfahan University of Medic

Full name of responsible person

Ahmad Esmailzadeh

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Person responsible for scientific inquiries

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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