

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Investigation the effect of hull-less barley bread on lipid profile, fasting blood sugar and effective factors on vascular endothelial function in hypercholesterolemic patients

Protocol summary

Summary

Increased lipid profile after each meal can disturb the endothelial function. The present study assessed the effects of bread supplemented with oat bran on serum lipids and endothelial dysfunction in patients with hypercholesterolemia. This randomized controlled clinical trial was conducted on 60 patients (age: 20-60 years old) who were receiving statins for hypercholesterolemia. The subjects were selected from hypercholesterolemic participants in outpatient clinics. Individuals with diabetes type one or two, hypothyroidism, renal failure, anemia, cholestasis, pancreatic cancer or malignancy, and secondary dyslipidemia were not included. Patients who used antihypertensive drugs or alcohol, smoked, did vigorous regular exercise, had a history of eating disorders, or had weight changes (losing or gaining more than three kilogram weight during the three months prior to the study) were not included, either. The subjects were randomly allocated to either intervention (consuming at least five daily servings of oat bread with 6 g beta-glucagon) or control (receiving at least five servings of wheat bread). Anthropometric indicators, fasting blood sugar and lipid profiles were measured at baseline and in the end of intervention. Endothelial function was assessed using flow-mediated dilation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312073733N3**
Registration date: **2014-01-03, 1392/10/13**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-03, 1392/10/13

Registrant information

Name

Masoumeh Sadeghi

Name of organization / entity

Isfahan Cardiovascular Research Center, Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan Cardiovascular Research Institute, Isfahan University of Medical Sciences

Expected recruitment start date

2013-01-01, 1391/10/12

Expected recruitment end date

2013-03-01, 1391/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of hull-less barley bread on lipid profile, fasting blood sugar and effective factors on vascular endothelial function in hypercholesterolemic patients

Public title

Investigation the effect of hull-less barley bread on lipid

profile, fasting blood sugar and effective factors on vascular endothelial function in hypercholesterolemic patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age 25-65 years old; hypercholesterolemia patients who receiving statins for hypercholesterolemia. Exclusion criteria: Diabetes type one or two; hypothyroidism; renal failure; anemia; cholestasis; pancreatic cancer or malignancy; secondary dyslipidemia; used antihypertensive drugs; alcohol; smoked; did regular exercise; had a history of eating disorder; had weight changes (losing or gaining more than three kilogram weight during the three months prior to the study)

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan Cardiovascular Research Institute Isfahan
University of Medical Sciences

Street address

Isfahan Cardiovascular Research Institute, Khorram,
Ave

City

Isfahan

Postal code

Approval date

2012-10-27, 1391/08/06

Ethics committee reference number

91117

Health conditions studied

1

Description of health condition studied

Hypercholesterolemic

ICD-10 code

E78.0

ICD-10 code description

Low-density-lipoprotein-type [LDL]
hyperlipoproteinaemia

Primary outcomes

1

Description

Lipid Profile

Timepoint

Before and after intervention

Method of measurement

Autoanalyzer

2

Description

Fasting blood sugar

Timepoint

Before and after intervention

Method of measurement

Autoanalyzer

3

Description

flow-mediated dilation (FMD)

Timepoint

Before and after intervention

Method of measurement

FMD is a noninvasive technique where forearm ischemia is induced by inflating a sphygmomanometer cuff to 50-100 mmHg for five minutes.

Secondary outcomes

1

Description

Body mass index

Timepoint

before and after intervention

Method of measurement

Body mass index (BMI) was calculated as weight divided by height squared

2

Description

Hip circumference

Timepoint

before and after intervention

Method of measurement

measured based on standard protocols.

3

Description

waist circumference

Timepoint

before and after intervention

Method of measurement

measured based on standard protocols.

4

Description

blood pressure

Timepoint

before and after intervention

Method of measurement

after 20-minuterest, in sitting position

Intervention groups

1

Description

All subjects were provided with a hypo caloric diet in the calorie range of 1500- 2000 for 4 weeks. the intervention group received the hypocaloric diet containing an experimental bread rich in beta-glucan from oat bran (at least five servings (150 g) per day based on their needs, each serving of which had 6 gram beta-glucan). Their adherence to diet was checked weekly by a dietitian through a diary log in which the daily amounts of all consumed foods including bread were recorded. They were asked to continue their routine levels of physical activity and not to consume fiber supplements, weight loss drugs, herbals medicines, or laxatives. During the course of the intervention, the participants attended weekly visits with the mentioned resident and nutritionist (who evaluated their daily intake of food items).

Category

Prevention

2

Description

All subjects were provided with a hypo caloric diet in the calorie range of 1500- 2000 for 4 weeks. The control group consumed the hypocaloric diet with control bread rich in wheat fiber (at least five servings (150 g) per day based on their needs, with no beta-glucan). Their adherence to diet was checked weekly by a dietitian through a diary log in which the daily amounts of all consumed foods including bread were recorded. They were asked to continue their routine levels of physical activity and not to consume fiber supplements, weight loss drugs, herbals medicines, or laxatives. During the course of the intervention, the participants attended weekly visits with the mentioned resident and nutritionist (who evaluated their daily intake of food items).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Cardiovascular Research Institute

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan Cardiovascular Research Institute

Full name of responsible person

Dr. Masoumeh Sadeghi

Street address

Sedighe Tahereh Center, Khorram Ave, Jomhour square

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan Cardiovascular Research Institute

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Mr. Toghyani

Street address

School of Medicine, Isfahan University of Medical Sciences, Hezar jerib Ave

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source

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 Cardiovascular Research Institute

Full name of responsible person

Dr Hamidreza Roohafza

Position

Assistant Professor

Other areas of specialty/work

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Associate Professor

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Web page address

Person responsible for updating data

Contact

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