

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of whole grains versus refined grains on fasting blood sugar in adults with impaired glucose tolerance: An unblinded, randomized, and crossover controlled trial.

Protocol summary

Study aim

To compare the effect of whole bread versus refined bread on fasting blood sugar in adults with syndrome metabolic.

Design

An unblinded, randomized, and crossover controlled trial.

Settings and conduct

A one-week run-in period will be conducted and then participants will be randomized using block balanced randomization of a four-block size via computer-generated randomization and allocated to an intervention group(A) and a comparison group(B). There are two 3-month treatment periods separated by a 4-week washout and then the intervention and comparison groups will swap places for an additional twelve weeks. The study will be implemented at the Diabetes Clinic of Tehran University in Tehran, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adults aged 25-64 who consume refined grains as part of their habitual diet and can be defined as metabolic syndrome patients based on the updated National Cholesterol Education Program (NCEP) Adult Treatment Panel III (ATP III) criteria and displaying three of the conditions below : 1) Abdominal obesity as defined as a waist circumference in women ≥ 80 cm and in men ≥ 94 cm based on the cutoff measurements of the Middle East (31) 2) Serum triglycerides ≥ 150 mg/dl (1.7mmol/l) 3) Serum high-density lipoprotein (HDL) cholesterol < 40 mg/dl (1 mmol/L) in men and < 50 mg/dl (1.3 mmol/l) in women 4) Blood pressure $\geq 130/85$ mmHg 5) Fasting plasma glucose (FPG) between 100-125mg/dl (5.6-6.9) mmol/l Exclusion criteria: • Individuals with a history of diabetes, cardiovascular diseases, cancer, kidney disease, gastrointestinal conditions or celiac disease. • Women who are pregnant or breast-feeding women

Intervention groups

The daily intake of rice and bread of each participant will be calculated based on the FFQ. Half of their serving of bread and rice will be replaced with whole wheat flatbread per day.

Main outcome variables

FBS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160111025947N2**

Registration date: **2018-05-09, 1397/02/19**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-09, 1397/02/19**

Update count: **0**

Registration date

2018-05-09, 1397/02/19

Registrant information

Name

Fatemeh Kazemi

Name of organization / entity

School of Nutrition Sciences and Dietetics Tehran
University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01
Expected recruitment end date
2018-06-21, 1397/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effect of whole grains versus refined grains on fasting blood sugar in adults with impaired glucose tolerance: An unblinded, randomized, and crossover controlled trial.

Public title

Whole grain in metabolic syndrome

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

1) Abdominal obesity as defined as a waist circumference in women ≥ 80 cm and in men ≥ 94 cm based on the cutoff measurements of the Middle East (31) 2) Serum triglycerides ≥ 150 mg/dl (1.7 mmol/l) 3) Serum high-density lipoprotein (HDL) cholesterol < 40 mg/dl (1 mmol/L) in men and < 50 mg/dl (1.3 mmol/l) in women 4) Blood pressure $\geq 130/85$ mmHg 5) Fasting plasma glucose (FPG) between 100-125 mg/dl (5.6-6.9) mmol/l 6) 25-64 years old

Exclusion criteria:

• Individuals with a history of diabetes, Individuals with a history of cardiovascular diseases, Individuals with a history of cancer, Individuals with a history of kidney disease, Individuals with a history of lower gastrointestinal conditions Individuals with a history of celiac disease. • Individuals taking medications which could influence lipid metabolism except for low-intensity Statin therapy, Individuals taking medications which could influence glucose metabolism except for Metformin up to 1000 mg/day Individuals taking medications which could influence blood pressure except for losartan up to 25 mg/day Women who are pregnant or may become pregnant during the duration of the study breast-feeding women

Age

From **25 years** old to **64 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

using block balanced randomization of a four-block size via computer-generated randomization (Microsoft Excel 2010).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Non-communicable Disorders Research Center of Endocrinology and Metabolism Research Institute, Tehra

Street address

No 10, Jalal al ahmad Alley,tehran

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Postal code

1411713119

Approval date

2015-10-13, 1394/07/21

Ethics committee reference number

IR.tums.EMRI.Rec.1394.23

Health conditions studied

1

Description of health condition studied

Metabolic Syndrome

ICD-10 code

E88.9

ICD-10 code description

Metabolic disorder, unspecified

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

before intervention and 3,4,7 months after intervention

Method of measurement

by Glucose oxidase method

Secondary outcomes

1

Description

Homeostatic Model Assessment of Insulin Resistance (HOMA-IR)

Timepoint

At the beginning of the study(before starting intervention), 3, 4,7 months after the intervention.

Method of measurement

by the following formula: (fastinginsulin ($\mu\text{U/ml}$) \times fasting glucose (mmol/l))/22.5)

2

Description

Plasma Total Cholesterol/HDL-C

Timepoint

At the beginning of the study(before starting intervention), 3, 4,7 months after the intervention.

Method of measurement

by the formula

3

Description

Triglyceride

Timepoint

At the beginning of the study(before starting intervention), 3, 4,7 months after the intervention.

Method of measurement

enzymatic method

4

Description

Total Cholesterol

Timepoint

At the beginning of the study(before starting intervention), 3, 4,7 months after the intervention.

Method of measurement

Enzymatic method

5

Description

Fasting plasma Insulin

Timepoint

At the beginning of the study(before starting intervention), 3, 4,7 months after the intervention.

Method of measurement

Elisa

6

Description

postprandial Insulin

Timepoint

At the beginning of the study(before starting intervention), 3, 4,7 months after the intervention.

Method of measurement

Elisa

7

Description

Postprandial glucose

Timepoint

At the beginning of the study(before starting intervention), 3, 4,7 months after the intervention.

Method of measurement

Glucose oxidase method

8

Description

High sensitivity C-reactive protein concentration(hs-CRP)

Timepoint

At the beginning of the study(before starting intervention), 3, 4,7 months after the intervention.

Method of measurement

Turbidimetric method

9

Description

Interleukin1(IL1)

Timepoint

At the beginning of the study(before starting intervention), 3, 4,7 months after the intervention.

Method of measurement

Enzymatic method

10

Description

Interleukin6(IL6)

Timepoint

At the beginning of the study(before starting intervention), 3, 4,7 months after the intervention.

Method of measurement

Enzymatic method

11

Description

Tumor Necrosis Factor- α (TNF- α),

Timepoint

At the beginning of the study(before starting intervention), 3, 4,7 months after the intervention.

Method of measurement

ELISA

12

Description

Hemoglobin A1c

Timepoint

At the beginning of the study(before starting intervention), 3, 4,7 months after the intervention.

Method of measurement

HPLC

13

Description

weight

Timepoint

At the beginning of the study(before starting intervention), 3, 4,7 months after the intervention.

Method of measurement

by scale

Intervention groups**1****Description**

Intervention group: Whole wheat flatbread

Category

Lifestyle

2**Description**

Control group: Refined wheat flatbread group

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

The diabetes clinic in Tehran, Iran.

Full name of responsible person

Fatemeh Kazemi

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Clinic Diabetes, 17Shahrivar St., Kargarshomali Ave

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Kazemi

Position

Ph.D. candidate

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable