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 ≥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

Iran (Islamic Republic of)

Phone

+98 21 8895 5975

Email address

f_kazemi@razi.tums.ac.ir

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 (1.7mmol/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 ≥130/85 mmHg 5) Fasting plasma glucose (FPG) between 100-125mg/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 1000mg/day Individuals taking medications which could influence blood pressuer except for losartan up to 25mg/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

City
Tehran

Province
Tehran

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 (μU/ml)) × 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-∝(TNF-∝),
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
Street address
Clinic Diabetes, 17Shahrivar St., Kargarshomali Ave
City
Tehran
Province
Tehran
Postal code
88984861
Phone
+98 21 8898 4861
Email
Kazemifatemeh4@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Farshad Farzadfar
Street address
Non-communicable Diseases Research Center - Endocrinology and Metabolism Research Institute, Tehran, Jallal alahmad Ave,
City
Tehran
Province
Tehran
Postal code
88955975
Phone
+98 21 8895 5975
Email
Kazemifatemeh4@gmail.com
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
Street address
Hojjat-dost Alley, Naderi St., Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
8895 5975
Phone
+98 21 8895 5975
Email
kazemifatemeh4@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Kazemi
Position
student
Latest degree
Ph.D.

Other areas of specialty/work
Nutrition
Street address
No.44, Hojjat-doost St., Naderi St., Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
8895 5975
Phone
+98 21 8895 5975
Fax
+98 21 8898 4861
Email
f_kazemi@razi.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Kazemi
Position
student
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
No.44, Hojjat-doost St., Naderi St., Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
8895 5975
Phone
+98 21 8895 5975
Fax
+98 21 8898 4861
Email
Kazemifatemeh4@gmail.com

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