

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

The effects of fortified-bread with pomegranate peel powder on anthropometric indices, lipid profile, glycemic indices, oxidative stress markers, mood and inflammation level in patients with type 2 diabetes

Protocol summary

Study aim

The aim of the present study is to evaluate the effects of fortified-bread with pomegranate peel powder consumption on anthropometric indices, lipid profile, glycemic indices, oxidative stress markers, and mood in patients with type 2 diabetes

Design

This is a randomized, double-blind placebo-controlled, clinical trial. Ninety participants will randomly be allocated to either fortified-bread with pomegranate peel powder (n = 45) or placebo (n = 45).

Settings and conduct

Type 2 diabetic participants aged 40–60 years will be recruited from Isfahan Endocrine & Metabolism Research Center (IEMRC), Isfahan, Iran. Subjects will be randomly divided into control and intervention groups by simple randomization. Random assignment will be done using a table of random numbers. Participants will consume fortified-bread with 3.5 percent pomegranate peel powder and regular-bread in the intervention and the placebo group, respectively. Participants will replace 100 grams of fortified- or whole-bread with their daily bread.

Participants/Inclusion and exclusion criteria

The cases will be enrolled in the study if they meet the following inclusion criteria 1) Willing to participate in the study; 2) Diagnosis of diabetes in the last 5 years; 3) Body mass index (BMI) <30; 4) Glycosylated hemoglobin less than 8. The exclusion criteria are as following 1) Individuals with a history of cancer, cardiovascular disease, renal, hepatic, and thyroid disorders; 2) Using insulin or oral insulin-stimulating agents.

Intervention groups

Individuals will randomly be divided into two groups to receive either 100g wheat-bread with 3.5 percent PPP or placebo, daily for 12 weeks.

Main outcome variables

Fasting glucose; glycosylated hemoglobin; fasting

insulin; serum lipid profile; mood status; inflammatory and antioxidant indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191209045672N1**

Registration date: **2020-09-21, 1399/06/31**

Registration timing: **prospective**

Last update: **2022-11-09, 1401/08/18**

Update count: **1**

Registration date

2020-09-21, 1399/06/31

Registrant information

Name

Maryam Zare

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

mehr_mzare74@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-01, 1399/07/10

Expected recruitment end date

2021-07-21, 1400/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effects of fortified-bread with pomegranate peel powder on anthropometric indices, lipid profile, glycemic indices, oxidative stress markers, mood and inflammation level in patients with type 2 diabetes

Public title
The effect of fortified- bread with pomegranate peel powder in the treatment of diabetes

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Age 40-60 Body mass index less than 30 Glycosylated hemoglobin less than 8 Willing to participate in the study, diagnosis of diabetes in the last 5 years Understanding the objectives of the study Written consent
Exclusion criteria:
No complications of diabetes Using insulin or oral agents inducing insulin secretion Smoking Pregnancy Lactation Taking antioxidant supplements within the last 3 months Having a history of cancer, cardiovascular disease, renal, hepatic and thyroid disorders before the intervention

Age
From **40 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
A stratified randomized permuted block(with block size 4) will be generated by an independent bio-statistician. Random assignment will be done by the use of a table of random numbers. The participant's enrollment and assignment to the groups will be carried out by a trained nutritionist.

Blinding (investigator's opinion)
Double blinded

Blinding description
Fortified-bread with pomegranate peel powder(PPP) and its placebo (wheat bread) will be manufactured by the Simin bread workshop (Isfahan, Iran). Both fortified-bread and its placebo provided by the Simin bread workshop will be packed for each patient according to the randomization sequence. Fortified-bread and its

placebo will be in similar packages and patients and researcher will not be aware of the content of the packages until the end of the trial. The intervention group will consume 100 gr of whole-wheat-bread with 3.5 percent PPP twice a week. The control group will consume 100 gr of whole-wheat-bread twice a week. The intervention will be continued for 3 months.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib Street,Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2020-05-12, 1399/02/23

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.087

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus type 2 due to underlying condition

Primary outcomes

1

Description

Effect of fortified-bread with pomegranate peel powder on FBS level

Timepoint

Before intervention and after 12 weeks consumption of fortified-bread with pomegranate peel powder

Method of measurement

Measurement by laboratory kit

2

Description

Effect of fortified-bread with pomegranate peel powder on HbA1c level

Timepoint

Before intervention and after 12 weeks consumption of fortified-bread with pomegranate peel powder

Method of measurement

Measurement by chromatography

3

Description

Effect of fortified-bread with pomegranate peel powder on insulin level

Timepoint

Before intervention and after 12 weeks consumption of fortified-bread with pomegranate peel powder

Method of measurement

Measurement by laboratory kit

4

Description

Effect of fortified-bread with pomegranate peel powder on lipid profile level

Timepoint

Before intervention and after 12 weeks consumption of fortified-bread with pomegranate peel powder

Method of measurement

Measurement by laboratory kit

5

Description

Effect of fortified-bread with pomegranate peel powder on Malon dealdehyde level

Timepoint

Before intervention and after 12 weeks consumption of fortified-bread with pomegranate peel powder

Method of measurement

Measurement by laboratory kit

6

Description

Effect of fortified-bread with pomegranate peel powder on total antioxidant capacity level

Timepoint

Before intervention and after 12 weeks consumption of fortified-bread with pomegranate peel powder

Method of measurement

Measurement by laboratory kit

7

Description

C-reactive protein measurement with high sensitivity

Timepoint

Before intervention and after 12 weeks consumption of fortified-bread with pomegranate peel powder

Method of measurement

Measurement by laboratory kit

Secondary outcomes

1

Description

Depression, anxiety and stress scales

Timepoint

Before intervention and after 12 weeks consumption of fortified bread with pomegranate peel powder

Method of measurement

Questionnaire

2

Description

weight

Timepoint

Before intervention and after 12 weeks consumption of fortified bread with pomegranate peel powder

Method of measurement

scales

3

Description

waist

Timepoint

Before intervention and after 12 weeks consumption of fortified bread with pomegranate peel powder

Method of measurement

Measuring meter

4

Description

blood pressure

Timepoint

Before intervention and after 12 weeks consumption of fortified bread with pomegranate peel powder

Method of measurement

Blood pressure measuring device

Intervention groups

1

Description

Intervention group: In this group, subjects will use 100 grams of enriched-bread with pomegranate peel powder daily for breakfast and snacks for 12 weeks.

Category

Treatment - Other

2

Description

Control group: In this group, subjects will consume 100 grams of regular wheat bread for 12 weeks for breakfast and snacks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Esfahan Endocrine Metabolic Research Center and Health centers

Full name of responsible person

Reza Amani

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Khoram Street, Isfahan Endocrine Metabolic Research Center and Ibn Sina Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Food Security Research Center, Isfahan University of Medical Sciences, Hezar Jarib Street

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Reza Amani

Position

Professor

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

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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