

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

The Effects of Intake of the Fortified Bread by Whey Protein Concentrate on Glycemic Control, Lipid Profile, Blood Pressure, Anthropometric Parameters, Resting Energy Expenditure, Oxidative Stress Markers and Appetite in Women With Type 2 Diabetes Mellitus

Protocol summary

Study aim

The Effects of Intake of the Fortified Bread by Whey Protein Concentrate on Glycemic Control, Lipid Profile, Blood Pressure, Anthropometric Parameters, Resting Energy Expenditure, Oxidative Stress Markers and Appetite in Women With Type 2 Diabetes Mellitus

Design

Parallel randomized controlled clinical trial with a sample size of 44 people

Settings and conduct

The practical stages of the study are carried out in Tabriz. Women with type 2 diabetes will be selected with an endocrinologist diagnosis.

Participants/Inclusion and exclusion criteria

Women with type 2 diabetes aged between 25-55 years. Patients who control their diabetes by glucose lowering tablets and do not use insulin. Inclusion criteria: 1) Willingness to cooperation 2) Women with type 2 diabetes mellitus 3) Women aged 25-55 years 4) Glucose lowering tablets usage 5) BMI= 25-35 kg/m² 6) GFR > 60 ml/min Exclusion criteria: 1) Unwillingness to cooperation 2) Patients with inflammatory, immunologic, psychologic, pulmonary, and neoplastic diseases 3) Patients with renal, hepatic, and thyroid disorders 4) Supplement intake 5) Use of corticosteroids, non-steroidal anti-inflammatory, and hormonal drugs 6) Change in type or dosage of used drugs during the study 7) Change in diet and physical activity during the study 8) Tobacco use 9) Use of insulin 10) Special physiologic conditions such as pregnancy, lactation, and menopause 11) Patients with malabsorption diseases such as sprue and Crohn's disease 12) Allergy or intolerance to milk components

Intervention groups

Qualified patients will be randomly divided into 2 groups of: Intervention group: Fortified whole bread by whey protein concentrate; Control group: Whole bread

Main outcome variables

Blood glucose, Oxidative stress markers: TAC, MDA

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110123005670N26**

Registration date: **2019-01-07, 1397/10/17**

Registration timing: **prospective**

Last update: **2019-01-07, 1397/10/17**

Update count: **0**

Registration date

2019-01-07, 1397/10/17

Registrant information

Name

Ali Tarighat-Esfanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 914 300 5895

Email address

tarighata@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-20, 1397/10/30

Expected recruitment end date

2019-04-20, 1398/01/31

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The Effects of Intake of the Fortified Bread by Whey Protein Concentrate on Glycemic Control, Lipid Profile, Blood Pressure, Anthropometric Parameters, Resting Energy Expenditure, Oxidative Stress Markers and Appetite in Women With Type 2 Diabetes Mellitus

Public title

The Effects of Intake of the Fortified Bread by Whey Protein Concentrate in Women With Type 2 Diabetes Mellitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to cooperation Women with type 2 diabetes mellitus Women aged 25-55 years glucose lowering tablets usage BMI= 25-35 kg/m² GFR > 60 ml/min

Exclusion criteria:

Unwillingness to cooperation Patients with inflammatory, immunologic, psychologic, pulmonary, and neoplastic diseases Patients with renal, hepatic, and thyroid disorders Supplement intake Use of corticosteroids, non-steroidal anti-inflammatory, and hormonal drugs Change in type or dosage of used drugs during the study Change in diet and physical activity during the study Tobacco use Use of insulin Special physiologic conditions such as pregnancy, lactation, and menopause Patients with malabsorption diseases such as sprue and Crohn's disease Allergy or intolerance to milk components

Age

From **25 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Women who have the inclusion criteria, will be divided to intervention and placebo groups via simple randomization method.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2018-11-19, 1397/08/28

Ethics committee reference number

IR.TBZMED.REC.1397.687

Health conditions studied

1

Description of health condition studied

type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Fasting Blood Glucose

Timepoint

Before the intervention and 90 days after the start of the intervention

Method of measurement

Enzymatic by commercial kits

2

Description

Insulin

Timepoint

Before the intervention and 90 days after the start of the intervention

Method of measurement

ELISA

3

Description

Hemoglobin A1C

Timepoint

Before the intervention and 90 days after the start of the intervention

Method of measurement

ELISA with commercial kits

4

Description

HOMA-IR

Timepoint

Before the intervention and 90 days after the start of the intervention

Method of measurement

Calculation

5

Description

Triglyceride

Timepoint

Before the intervention and 90 days after the start of the intervention

Method of measurement

Enzymatic

6

Description

HDL-Cholesterol

Timepoint

Before the intervention and 90 days after the start of the intervention

Method of measurement

Enzymatic

7

Description

MDA

Timepoint

Before the intervention and 90 days after the start of the intervention

Method of measurement

spectrophotometry

8

Description

TAC

Timepoint

Before the intervention and 90 days after the start of the intervention

Method of measurement

spectrophotometry

Secondary outcomes

1

Description

Blood Pressure

Timepoint

Before the intervention and 90 days after the start of the intervention

Method of measurement

Digital Barometer

2

Description

Weight

Timepoint

Before the intervention and 90 days after the start of the intervention

Method of measurement

Scale

3

Description

Body Mass Index (BMI)

Timepoint

Before the intervention and 90 days after the start of the intervention

Method of measurement

Computing

4

Description

Body fat percent

Timepoint

Before the intervention and 90 days after the start of the intervention

Method of measurement

Bio impedance set

5

Description

waist circumference

Timepoint

Before the intervention and 90 days after the start of the intervention

Method of measurement

measurement by meter

6

Description

Hip circumference

Timepoint

Before the intervention and 90 days after the start of the intervention

Method of measurement

measurement by meter

7

Description

WHR

Timepoint

Before the intervention and 90 days after the start of the intervention

Method of measurement

Computing

8**Description**

Appetite

Timepoint

Before the intervention and 90 days after the start of the intervention

Method of measurement

Appetite Assessment Questionnaire

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

Intervention group: About 120 g fortified whole bread by whey protein concentrate per day for 90 days

Category

Treatment - Other

2**Description**

Control group: About 120 g whole bread per day for 90 days

Category

Other

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

Imam Reza Hospital

Full name of responsible person

Maryam Nouri

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Golgasht Street

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East Azarbaijan

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

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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

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Ali Tarighat-Esfanjani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Maryam Nouri

Position

Ph.D candidate

Latest degree

Master

Other areas of specialty/work

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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