

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### The effects of bread containing Fenugreek and Cinnamon on anthropometric indices, glycemic status and lipid profile in patients with type 2 diabetes mellitus

#### Protocol summary

##### Study aim

Determining the effect toast contains fenugreek and cinnamon on glucose control in patients with diabetes

##### Design

Randomized controlled clinical trial with a parallel group Phase 2 of 100 patients. Which the random function of Excel software was used for randomization.

##### Settings and conduct

Eligible patients will be selected by the announcement and referring by physicians among those referred to Diabetic clinics affiliated to Tehran University of Medical Sciences. Before starting the trial, the study will be explained to eligible individuals and if they have the tendency to participate, they will sign the written informed consent. Due to the type of intervention in this study, complete blindness is not possible. However, a colleague who will analysis data is not aware of the groups. Finally, encoded data will be provided to the data analysis team.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with type 2 diabetes mellitus taking oral anti-diabetic medications Age 30 to 70 years Lack of liver and kidney disease, uncontrolled thyroid and other complications of diabetes leading to inflammatory and oxidative conditions, other types of diabetes Not pregnant or breastfeeding

##### Intervention groups

The first group :toast contains fenugreek and cinnamon  
The second group :placebo toast (containing wheat flour)  
The third group : common breads

##### Main outcome variables

Fasting blood sugar, glycosylated hemoglobin and anthropometric indicators

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110314006065N4**  
Registration date: **2022-02-21, 1400/12/02**  
Registration timing: **registered\_while\_recruiting**

Last update: **2022-02-21, 1400/12/02**

Update count: **0**

##### Registration date

2022-02-21, 1400/12/02

##### Registrant information

##### Name

Nazli Namazi

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6694 9630

##### Email address

nazli.namazi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-23, 1400/10/02

##### Expected recruitment end date

2022-04-10, 1401/01/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of bread containing Fenugreek and Cinnamon on anthropometric indices, glycemic status and lipid profile in patients with type 2 diabetes mellitus

#### Public title

The effects of bread containing Fenugreek on health of patients with type 2 diabetes mellitus

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with type 2 diabetes (fasting blood sugar less than or equal to 126 Milligrams in deciliter and two-hour blood sugar greater than or equal to 200 Milligrams in deciliter) Receiving blood sugar lowering drugs HbA1c more than 10% Body mass index less than 40 kilogram in square meter

##### Exclusion criteria:

Insulin or liraglutide injection Type 1 diabetes History of chronic liver and kidney disease, diabetic foot ulcer, various malignancies, rheumatic and infectious diseases

- Take any herbal medicine or herbal medicine to control blood sugar at present History of any allergies to herbs

Pregnant or lactating women

#### Age

From **20 years** old to **50 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

- Investigator
- Data analyser

#### Sample size

Target sample size: **90**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Patients are randomly divided (six random blocks) into three groups of 30. One group eats toast containing fenugreek and cinnamon, the second group eats placebo toast (containing wheat flour) and the third group eats common breads. Randomization is done using an online system (<https://www.sealedenvelope.com/>). After randomization, each patient is given a code that is identified during the study. The random number is assigned sequentially. Randomization is not visible to those conducting the study and is provided in matte and sealed envelopes with consecutive numbers. The envelope is opened after patients sign the informed consent form and meet the eligibility criteria.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Envelopes containing fortified bread and not fortified toast will be exactly the same in shape, color and size of packaging and will be stored in dark packaging. The packages will be named A and B, and the researcher does not know which bread each group uses.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

#### Ethics committees

##### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Endocrinology & Metabolism Research Institute

###### Street address

Endocrinology & Metabolism Research Institute, Shariati Hospital, North Kargar Avenue

###### City

Tehran

###### Province

Tehran

###### Postal code

1411713137

##### Approval date

2021-05-09, 1400/02/19

##### Ethics committee reference number

IR.TUMS.EMRI.REC.1400.041

#### Health conditions studied

##### 1

##### Description of health condition studied

Type 2 diabetes

##### ICD-10 code

E08

##### ICD-10 code description

Diabetes mellitus due to underlying condition

#### Primary outcomes

##### 1

##### Description

fasting blood sugar

##### Timepoint

Baseline, after 8 weeks of the intervention (At the end of the intervention)

##### Method of measurement

Autoanalyzer

#### Secondary outcomes

##### 1

##### Description

HbA1c

##### Timepoint

Baseline, after 8 weeks of the intervention (At the end of

the intervention)

**Method of measurement**

En Chromatography

**2**

**Description**

weight

**Timepoint**

Baseline, after 8 weeks of the intervention (At the end of the intervention)

**Method of measurement**

Scales

**3**

**Description**

Total cholesterol

**Timepoint**

Baseline, after 8 weeks of the intervention (At the end of the intervention)

**Method of measurement**

Autoanalyzer

**Intervention groups**

**1**

**Description**

Intervention group: Group consumes a toast containing fenugreek and cinnamon. Baked bread will replace 4 units of common bread and the study will continue for 8 weeks. Carbohydrates will be considered for all three study groups, taking into account 55% of carbohydrates consumed daily.

**Category**

Treatment - Other

**2**

**Description**

Intervention group: The second group consumes placebo toast (containing wheat flour). Baked bread will replace 4 units of common bread and the study will continue for 8 weeks. Carbohydrates will be considered for all three study groups, taking into account 55% of carbohydrates consumed daily.

**Category**

Treatment - Other

**3**

**Description**

Control group: Control group: Consume common breads. .study will continue for 8 weeks. Carbohydrates will be considered for all three study groups, taking into account 55% of carbohydrates consumed daily.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Endocrinology and Metabolism Research Institute

**Full name of responsible person**

Nazli Namazi

**Street address**

Endocrinology & Metabolism Research Institute, Shariati Hospital, North Kargar Avenue

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713137

**Phone**

+98 21 8863 1298

**Email**

nazli.namazi@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr.Akbar Fotuhi

**Street address**

Vice Chancellor of Research and Technology Tehran University of Medical Sciences, Ghods Street, Keshavarz Square, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713137

**Phone**

+98 21 8863 1298

**Email**

nazli.namazi@yahoo.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**

Nazli Namazi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Endocrinology & Metabolism Research Institute,  
Shariati Hospital, North Kargar Avenue

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713137

**Phone**

+98 919 241 4658

**Email**

nazli.namazi@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Nazli Namazi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Endocrinology & Metabolism Research Institute,  
Shariati Hospital, North Kargar Avenue

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713137

**Phone**

+98 919 241 4658

**Email**

nazli.namazi@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Nazli Namazi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Endocrinology & Metabolism Research Institute,  
Shariati Hospital, North Kargar Avenue

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713137

**Phone**

+98 919 241 4658

**Email**

nazli.namazi@yahoo.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**

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