

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### The effect of bread containing cumin on blood sugar in type 2 diabetic patients

#### Protocol summary

##### Study aim

The effect of bread containing cumin on blood sugar in type 2 diabetic patients

##### Design

A trial with a control group, with parallel, double-blind, randomized groups, is performed on 60 type 2 diabetes patients. randomization method is Stratified Intervention group: Bread cumin cumin Control group: Placebo bread

##### Settings and conduct

The study will be conducted at the Yazd Diabetes Research Center. 60 type 2 diabetic patients with medical records and being treated with oral drugs with inclusion criteria will be included in the study. Then the volunteers are randomly stratified (based on age, gender and average HbA1c) divided into two equal intervention and control groups. In the intervention group, daily amount of 120 grams of new formula bread (cumin bread) is given for consumption by all family members for 2 months and it is recommended to include said bread as part of their three meals. It is also recommended that they do not change their usual diet and physical activity level during the study period. In the control group, bread without cumin (of the same quality) is given. At the beginning and end of the study, weight, height, HbA1c and blood lipid profile (T.G, CHOL, both experimental groups) will be measured.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Type 2 diabetes patients with HbA1c<9 2) Male and female between 30 years old and older living in Yazd 3) Absence of chronic systemic diseases (liver, kidney, Neurological and psychiatric diseases) Exclusion criteria: 1) Drug and alcohol addiction 2) Special diets 3) Participation in special sports programs (championship sports) 4) Insulin use 5) Creatinine higher than 1.2 6) Medical reasons (chronic systemic diseases and mental-psychological diseases) 7) Pregnancy or breastfeeding

##### Intervention groups

Intervention group: Bread cumin Control group: Placebo

bread

##### Main outcome variables

HbA1c

#### General information

##### Reason for update

Change of financial support source; Due to the high costs, financial problems of Shahid Sadoughi Yazd University of Medical Sciences, and the failure to provide timely funding for the project, financial support from the private sector was used.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160221026684N4**

Registration date: **2022-12-31, 1401/10/10**

Registration timing: **prospective**

Last update: **2025-08-09, 1404/05/18**

Update count: **1**

##### Registration date

2022-12-31, 1401/10/10

##### Registrant information

###### Name

Seyed Ali Khodaie

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3728 0215

###### Email address

sa.khodaiei@shahed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-10, 1401/10/20

**Expected recruitment end date**

2023-08-22, 1402/05/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of bread containing cumin on blood sugar in type 2 diabetic patients

**Public title**

The effect of cumin bread on blood sugar in type 2 diabetic patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Type 2 diabetes HbA1c<9 At least 30 years old A resident of Yazd Absence of chronic systemic diseases

**Exclusion criteria:**

Drug and alcohol addiction Special diets Special sports programs Taking insulin Creatinine above 1.2 Pregnancy or breastfeeding Medical reasons (Chronic systemic diseases and mental-psychological diseases)

**Age**

From 30 years old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

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

**Sample size**

Target sample size: 60

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, 60 patients with type 2 diabetes and meeting the inclusion criteria will be selected. After determining all available samples, stratified random allocation will be done in three layers of age, gender and average HbA1c. First, all patients are divided into two groups based on gender, and from both groups, an equal number of women will be placed in both the intervention and control groups, and an equal number of men will be placed in the intervention and control groups. In the next step, all the patients who are assigned to two groups in terms of gender will be divided into four groups in terms of age and will be placed again in the intervention and control groups. Finally, we will have two groups of patients with similar age and gender distribution for intervention and control. Intervention allocation or random allocation is in the form of a closed envelope that the individual chooses before entering the

researcher's room. The envelope with the letter A will be the intervention group and B will be the control group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, only the main researchers are aware of the type of bread. The participating volunteers and other people involved in the project have no information about the type of bread. Both breads are similar in terms of shape, color, smell, packaging and appearance, and blinding has been done between them.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of shahid sadoughi university of medical sciences

**Street address**

Diabetes Research Center, Talar-e-Honar Alley, Shahid Sadoughi Blvd, Yazd

**City**

Yazd

**Province**

Yazd

**Postal code**

8917693571

**Approval date**

2022-12-14, 1401/09/23

**Ethics committee reference number**

IR.SSU.REC.1401.068

**Health conditions studied****1****Description of health condition studied**

Diabetes

**ICD-10 code**

E08

**ICD-10 code description**

Diabetes mellitus due to underlying condition

**Primary outcomes****1****Description**

HbA1c

**Timepoint**

At the beginning and end of the intervention (8 weeks

after the start)  
**Method of measurement**  
Chromatography (HPLC)

## Secondary outcomes

### 1

#### Description

Serum triglyceride level

#### Timepoint

At the beginning and end of the intervention (8 weeks after the start)

#### Method of measurement

Enzymatic method

### 2

#### Description

Serum total cholesterol level

#### Timepoint

At the beginning and end of the intervention (8 weeks after the start)

#### Method of measurement

Enzymatic method

## Intervention groups

### 1

#### Description

In the intervention group, it is recommended that the bread consumed by the diabetic patient should be cumin bread in all three meals and consume a total of 120 grams of cumin bread daily for 2 months (8 weeks). The bread consumed is delivered to the patient weekly. It was also emphasized to the study participants not to change their usual diet and physical activity level during the study period. Cumin bread: Bread made from wheat flour and cumin - the flour composition includes 96% wheat flour (with commercial name of Setareh) + 2% cumin powder + the remaining 2% includes yeast and permitted bread additives such as salt and standard ingredients that improve the quality of bread, which is converted into voluminous bread in the "Golnan Poratus" factory located in Karaj.

#### Category

Treatment - Other

### 2

#### Description

In the control group, it is recommended that the bread consumed by the diabetic patient be ordinary regular bread in all three meals and consume a total of 120 grams of this type of bread daily for 2 months (8 weeks). The bread consumed is delivered to the patient weekly. It was also emphasized to the study participants that they should not change their usual diet and physical activity level during the study period. ordinary bread: made from wheat flour - the flour composition includes 98% wheat flour (with commercial name of Setareh) +

the remaining 2% includes yeast and permitted bread additives such as salt and standard raw materials that improve the quality of the bread, which is converted into thick bread in the "Golnan Poratus" factory located in Karaj.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Yazd Diabetes Research Center

##### Full name of responsible person

Seyed Ali Khodaie

##### Street address

Talar-e-Hanar Alley, North Shahid Sadoughi Blvd

##### City

Yazd

##### Province

Yazd

##### Postal code

8917693571

##### Phone

+98 35 3728 0215

##### Fax

+98 35 3728 0216

##### Email

dr.seyedalikhodaie@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Behdane Baran Salem Abi

##### Full name of responsible person

Fariba Saeidi Gargary

##### Street address

Number 13-Unit 6-Second Floor- West Nosrat Street - Tohid Square

##### City

Tehran

##### Province

Tehran

##### Postal code

1457785588

##### Phone

+98 21 6657 6805

##### Email

mkamalinejad@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

Behdane Baran Salem Abi

#### Proportion provided by this source

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Other

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Seyed Ali Khodaie

**Position**

Non-academic specialist physician

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

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**Contact**

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**Contact**

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**Sharing plan**

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

HbA1c data : Data on the main outcome will be made available to other researchers with the permission of the first executor

**When the data will become available and for how long**

Starting one year after publication

**To whom data/document is available**

People working in academic institutions

**Under which criteria data/document could be used**

Coordinate with project analyzer

**From where data/document is obtainable**

Dr. Seyed ali Khodaie :03537280215  
dr.seyedalikhodaie@yahoo.com

**What processes are involved for a request to access data/document**

Request data from Yazd University of Medical Sciences,  
approval of the director of the Diabetes Research Center,  
approval of the first executor of the project

**Comments**