

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

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Talar-e-Hanar Alley, North Shahid Sadoughi Blvd

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Phone

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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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Person responsible for updating data

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