

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of glycemic index of bread based on cumin in healthy individuals

Protocol summary

Study aim

Evaluation of glycemic index of bread containing cumin in healthy individuals

Design

A trial with a control group, with parallel, double-blind, randomized groups, is performed on 20 healthy individuals. randomization method is Stratified
Intervention group: Bread prepared from cumin Control group: ordinary bread

Settings and conduct

The study will be conducted at the Yazd Diabetes Research Center. First, on 3 separate days, at least one day apart, everyone receives 50 grams of glucose dissolved in a cup of tea as a standard meal. On the fourth day of the study, individuals are randomly divided into two equal groups. The first group eats 100 grams of bread made from whole wheat flour and the second group eats 100 grams of bread designed based on a mixture of whole wheat flour and 2% cumin powder (Bread prepared from cumin) with a cup of tea. Every 4 days of the test, fasting blood sugar will be measured with a glucometer at 15, 30, 45, 60, 90 and 120 minutes after eating.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age: 20 to 45 years No known disease
Body mass index in the range of 18-25 Exclusion criteria: FBS>105 mg/dl Smoker Opioid addiction Pregnancy and Breast feeding special diet Professional sports exercises Metabolic disorders Taking drugs that affect blood glucose metabolism

Intervention groups

Intervention group: Bread prepared from cumin Control group: ordinary bread

Main outcome variables

Glycemic index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160221026684N3**

Registration date: **2022-03-19, 1400/12/28**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-19, 1400/12/28**

Update count: **0**

Registration date

2022-03-19, 1400/12/28

Registrant information

Name

Seyed Ali Khodaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3728 0215

Email address

sa.khodaie@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-06, 1400/12/15

Expected recruitment end date

2022-06-05, 1401/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of glycemic index of bread based on cumin in healthy individuals

Public title

Determination of glycemic index of bread containing cumin

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age: 20 to 45 years No known disease Body mass index in the range of 18-25

Exclusion criteria:

FBS>105 mg/dl Smoker Opioid addiction Pregnancy and Breast feeding special diet Professional sports exercises Metabolic disorders Taking drugs that affect blood glucose metabolism

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

In terms of gender, age and body mass index, stratified randomization is performed. First, we prepare a complete list of volunteers to participate in the study, then based on age, sex and body mass index, it will be divided into three groups and randomization will be done in each layer. Finally, based on the above criteria, we will have two groups of random and layered.

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

2022-03-02, 1400/12/11

Ethics committee reference number

IR.SSU.REC.1400.239

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

Healthy people

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Glycemic index

Timepoint

Measurement of fasting blood glucose and times of 15, 30, 45, 60, 90 and 120 minutes after eating glucose solution and each of the breads, in four non-consecutive days

Method of measurement

Using glucometer device and formula

Secondary outcomes

empty

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

Intervention group: Bread made from whole wheat flour and cumin- Flour composition includes 96% whole wheat flour + 2% cumin powder + 2% The rest includes dough and permitted bread additives such as salt and standard ingredients to improve the quality of bread, which is turned into bulk bread in "Golnan Puratos" factory.

Category

Prevention

2

Description

Control group: Bread made from whole wheat flour- The flour composition includes 98% whole wheat flour + the remaining 2%, including sourdough and authorized bread additives such as salt and standard ingredients that improve the quality of bread, which is converted into bulk bread in "Golnan Puratos" factory.

Category

Prevention

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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Email

dr.seyedalikhodaie@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amir Houshang Mehrparvar

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ah.mehrparvar@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Yazd 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

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 scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Seyed Ali Khodaie

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Person responsible for updating data

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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

Glycemic Index 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 6 months 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