

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of glycemic index of bread containing cumin in healthy individuals

Protocol summary

Study aim

Evaluation of satiety index of cumin-based bread in healthy individuals

Design

Clinical trial, crossover, controlled

Settings and conduct

The study is conducted at Yazd Diabetes Research Center. The study will be conducted on 2 separate days, one week apart. First, people are randomly divided into two equal groups. On the first day, the first group ate 90 grams of white bread and the second group ate 90 grams of bread designed based on the formulation of a mixture of whole wheat flour and 2% cumin powder (bread containing cumin) along with a glass containing 220 ml of water. On the second day, the first group will receive 90 grams of cumin-containing bread and the second group will receive 90 grams of white bread. On every 2 days of the experiment, after fasting for 10-12 hours, the participants will be asked to rate their feeling of fullness while fasting and at the time of 15, 30, 45, 60, 90 and 120 minutes after eating using the VAS questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age: 20 to 50 years old; healthy individuals; Body mass index in the range of 18.5-25; usual diet. Exclusion criteria: FBS>105 mg/dl; Smoker; opioid addiction; pregnancy and breast feeding; special diet; professional sports exercises; digestive disorders; metabolic disorders; bariatric surgery and taking drugs that affect blood sugar metabolism; gastric emptying; weight and appetite.

Intervention groups

Intervention group: bread containing cumin; control group: white bread

Main outcome variables

Satiety index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160221026684N5**

Registration date: **2023-09-27, 1402/07/05**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-27, 1402/07/05**

Update count: **0**

Registration date

2023-09-27, 1402/07/05

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

2023-09-23, 1402/07/01

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of glycemic index of bread containing cumin in healthy individuals

Public title
Determining the satiety index of bread containing cumin

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Healthy people $18.5 < \text{BMI} < 25$ Have a usual diet
Exclusion criteria:
FBS>105 mg/dl Smoker Opioid addiction Pregnancy and Breast feeding Special diet Professional sports exercises Metabolic disorders Digestive disorders Bariatric surgery Taking drugs that affect blood sugar metabolism, gastric emptying, weight and appetite

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

Gender
Both

Phase
N/A

Groups that have been masked

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

Sample size
Target sample size: **10**

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

2023-06-14, 1402/03/24

Ethics committee reference number

IR.SSU.REC.1402.035

Health conditions studied

1

Description of health condition studied

Healthy people

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Satiety index

Timepoint

Measure satiety in fasting and every 15 minutes after eating each bread for up to two hours in the first week and second week

Method of measurement

Using the VAS Questionnaire 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

Category

Prevention

2

Description

Control group: Bread made from white wheat flour - The flour composition includes 98% white wheat flour + the remaining 2%, including sourdough and authorized bread additives such as salt and standard ingredients that improve the quality of bread

Category

Prevention

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

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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

Amin Salehi Abargouei

Street address

Talar-e-Hanar Alley, North Shahid Sadoughi Blvd

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Email

abargoui@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

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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

Satiety 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