

# 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 < 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

**City**

yazd

**Province**

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**Postal code**

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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

**City**

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**Province**

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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**

**Name of organization / entity**

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**Person responsible for updating data**

**Contact**

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Yazd University of Medical Sciences

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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**