

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

the effect of the glycemic index, glycemic load and satiety index of breads made with wheat flour-barley flour and wheat flour-oat flour in healthy subjects

Protocol summary

Study aim

Determination of glycemic index, glycemic load and satiety index of breads prepared from wheat flour-barley and wheat flour-oat flour in healthy individuals

Design

Randomized, not blinded, clinical trial in Phase 3 and for the determining the satiety index 30 healthy individuals are sufficient.

Settings and conduct

In this study will be participate 10 healthy people for determining the glycemic index (GI) and load (GL), and 20 healthy people for determining the satiety index (SI). At the beginning, people are referred to the laboratory after 10-12 hours fasting and a FBS sample is taken from them. Then glucose solution, breads containing white flour, white flour mixed by barley flour (with different proportions), and oat flour (with different proportions) are given to individuals. Then, for determining of the GI and GL, blood samples will be taken at intervals of 30, 15, 45, 60, 90 and 120 minutes after eating. and for determining of SI, the questionnaire will determine the amount of satiety of individuals at fasting times and every 15 minutes to 120 minutes after eating breads containing white flour, white flour mixed by barley flour (with different proportions) and oat flour (with different proportions).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Both sexes; ages 20-40 years; FBS levels (< 110 mg / dl) and BMI (18.5 to 24.9 kg / m²) within the normal range; following a common diet
exclusion criteria: Pregnancy; Breast feeding; the use of drugs and diseases that affect the metabolism of blood sugar and the amount of the satiety and hunger

Intervention groups

Healthy people consume white bread, bread mixed with white flour and barley flour (with different proportions) and bread mixed with white flour and oat flour (with

different proportions)

Main outcome variables

Glycemic index; glycemic load; satiety index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180522039780N1**

Registration date: **2018-06-19, 1397/03/29**

Registration timing: **retrospective**

Last update: **2018-07-02, 1397/04/11**

Update count: **1**

Registration date

2018-06-19, 1397/03/29

Registrant information

Name

Mohadeseh Zendehehdel

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-02, 1396/11/13

Expected recruitment end date

2018-05-03, 1397/02/13

Actual recruitment start date

2018-02-02, 1396/11/13

Actual recruitment end date

2018-05-03, 1397/02/13

Trial completion date

empty

Scientific title

the effect of the glycemic index, glycemic load and satiety index of breads made with wheat flour-barley flour and wheat flour-oat flour in healthy subjects

Public title

Determination of glycemic index, glycemic load and the satiety index of breads made with wheat flour-barley flour and wheat flour-oat flour in healthy subjects

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

The level of fasting blood glucose is normal (less than 110 mg / ml) BMI normal (18.5 to 24.9) Follow the normal dietBMI

Exclusion criteria:**Age**

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

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

Ethics Committee of Ahwaz University of Medical Sciences

Street address

Golestan Highway

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2018-01-15, 1396/10/25

Ethics committee reference number

IR.AJUMS.REC.1396.869

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, the second week, the third week, forth week and fifth week.

Method of measurement

Using the VAS Questionnaire and Formula

2**Description**

Glycemic index

Timepoint

Measurement of fasting and accurate fasting blood glucose levels at 15, 30, 45, 60, 90 and 120 after glucose and any of the breads in the first, second, third, fourth and fifth weeks.

Method of measurement

Using the glucometer device

Secondary outcomes**1****Description**

Glycemic load

Timepoint

First week, second week, third week, forth week, fifth week, sixth week

Method of measurement

Using formula

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

Intervention group: Breads made with white wheat flour

Category

Lifestyle

2**Description**

Intervention group: Bread made from blend of barley flour and white flour to a ratio of 1/2

Category

Lifestyle

3**Description**

Intervention group: Bread made from blend of barley flour and white flour to a ratio of 1/4

Category

Lifestyle

4**Description**

Intervention group: Bread made from blend of oat flour and white flour to a ratio of 1/2

Category

Lifestyle

5**Description**

Intervention group: Bread made from blend of oat flour and white flour to a ratio of 1/4

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Nutrition and Metabolic Diseases Research Center

Full name of responsible person

Farideh Shishehbor

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

40

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**

Ahvaz University of Medical Sciences

Full name of responsible person

Mohaddese Zendeheel

Position

Masters of Nutrition

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Person responsible for updating data

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available