Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of soybean flour on the glycemic index, glycemic load and satiety index of white bread in healthy subjects

Protocol summary

Study aim

The effect of soybean flour on glycemic index, glycemic load,satiety index of white bread in healthy subjects

Design

Clinical trial, crossover, controlled

Settings and conduct

To determine the glycemic index and load, 10 healthy people with a normal blood sugar level will participate in the study. In each day of the study, people are referred to the laboratory after 10-12 hours fasting and a fasting blood sample is taken from them.Then glucose, white bread or two breads containing white flour and soybean flour are given to individuals. After that, blood samples will be taken at intervals of 30, 15, 45, 60, 90 and 120 minutes after eating.In order to determine the satiety index, 20 healthy people refer to the laboratory in the fasting state for three separate days, one week after 10-12 hours fasting. Before and after eating white bread and breads containing white flour and soybean flour, the questionnaire will determine the amount of satiety of individuals at fasting times and every 15 minutes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ages 20-40 years; Fasting blood sugar levels less than 110 mg / dl; Body mass index in the normal range (18.5 to 24.9 kg / m 2); following a common diet exclusion criteria: Pregnancy; Breast feeding; using drugs and diseases that affect metabolism of blood sugar and satiety and hunger.

Intervention groups

In intervention groups, 3 types of breads will be given, that each should contain 50 grams of available carbohydrates. Intervention group 1: white wheat flour bread Intervention group 2: bread made of equal amounts of soybean flour and white flour Intervention group 3: bread made of a mixture of 25% soybean flour and 75% white flour Control group: consuming glucose solution (50 grams of glucose dissolved in 250 ml of water)

Main outcome variables

Glycemic index; glycemic load; satiety index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181017041366N1**
Registration date: **2018-12-19, 1397/09/28**
Registration timing: **prospective**

Last update: **2018-12-19, 1397/09/28**
Update count: **0**

Registration date

2018-12-19, 1397/09/28

Registrant information

Name

Somayeh Mirzaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-10, 1397/10/20

Expected recruitment end date

2019-02-09, 1397/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of soybean flour on the glycemic index, glycemic load and satiety index of white bread in healthy subjects

Public title
Effect of soybean flour on the glycemic index, glycemic load and satiety index of white bread
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
The level of fasting blood glucose is normal (less than 110 mg / ml) Body mass index normal (18.5 to 24.9) Follow the normal diet
Exclusion criteria:
Taking medications that affect the metabolism of blood sugar and the amount of hunger and satiety. Diseases that affect the metabolism of blood sugar and the amount of hunger and satiety. Pregnancy Lactation
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 Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2018-10-14, 1397/07/22
Ethics committee reference number
IR.AJUMS.REC.1397.477

Health conditions studied

1

Description of health condition studied
glycemic index in healthy people
ICD-10 code
ICD-10 code description

2

Description of health condition studied
glycemic load in healthy people
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Satiety index in 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 and the third week
Method of measurement
Using the visual analog scale questionnaire and formula

2

Description
Glycemic index
Timepoint
Blood glucose measurements in fasting state and15، 30، 45، 60، 90، and 120 minutes after eating
Method of measurement
Using formula

Secondary outcomes

1

Description
Glycemic load
Timepoint

First week, second week, third week

Method of measurement

Using formula

Intervention groups

1

Description

Intervention group1: Each individual will consume a bread made of white wheat flour, water, improver, salt and yeast. This bread should contain 50 grams of available carbohydrates and 1,000 Kilojoules (240 kilocalories) of energy.

Category

Lifestyle

2

Description

Intervention group 2: Each individual will consume a bread made of a mixture of equal amounts of soybean flour and white flour, water, improver, salt and dough. This bread should contain 50 grams of available carbohydrates and 1,000 Kilojoules (240 kilocalories) of energy.

Category

Lifestyle

3

Description

Intervention group 3: Each individual will consume a bread made of a mixture of 25% soybean flour and 75% white flour, water, improver, salt and dough. This bread should contain 50 grams of available carbohydrates and 1,000 Kilojoules (240 kilocalories) of energy.

Category

Lifestyle

4

Description

Control group: Glucose solution (50 g dissolved in 250 ml of water) used to determine the glycemic index as a reference food.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Nutrition and Metabolic Disease Research Center, Ahvaz Jundishapur University of Medical Sciences

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

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

Ahvaz University of Medical Sciences

Full name of responsible person

Somayeh Mirzaei

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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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