

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of the effect of consuming the prepared cakes with acorn flour and wheat flour following a hypocaloric diet on serum levels of adiponectin, inflammatory factors and oxidative stress parameters in obese and overweight patients with metabolic syndrome: a double-blind clinical trial

Protocol summary

Study aim

Comparison of the effect of consuming the prepared cakes with acorn flour and wheat flour following a hypocaloric diet on serum levels of adiponectin, inflammatory factors and oxidative stress parameters in obese and overweight patients with metabolic syndrome

Design

In this double-blind randomized placebo-controlled study, 66 patients will randomly divide into 2 groups using the balanced block randomization method as follows: Group A (n=33) will receive 30 grams of oak cake once a day + a balanced hypocaloric diet Group B (n=33) will receive 30 grams of wheat cake once a day + a balanced hypocaloric diet This process is followed for 8 weeks.

Settings and conduct

This is a double-blind randomized study that is conducted for 8 weeks. Patients are divided into two groups receiving oak cake and wheat cake. All patients receive a balanced hypocaloric diet. Body composition and biochemical markers are measured before and after the intervention. Sampling location: Nutrition clinic of Imam Reza Clinic in Shiraz

Participants/Inclusion and exclusion criteria

Metabolic syndrome patients with overweight and obesity aged 20 to 60 according to ATP III criteria

Intervention groups

The group receiving 30 grams of oak cake once a day + balanced hypocaloric diet The group receiving 30 grams of wheat cake once a day + balanced hypocaloric diet

Main outcome variables

Insulin resistance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231104059958N1**

Registration date: **2023-11-19, 1402/08/28**

Registration timing: **retrospective**

Last update: **2023-11-19, 1402/08/28**

Update count: **0**

Registration date

2023-11-19, 1402/08/28

Registrant information

Name

Hamed Sadeghi-dehsahraei

Name of organization / entity

The University of Shiraz

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

2022-06-22, 1401/04/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

2022-06-25, 1401/04/04

Actual recruitment end date

2022-12-01, 1401/09/10

Trial completion date

2023-01-05, 1401/10/15

Scientific title

Comparison of the effect of consuming the prepared cakes with acorn flour and wheat flour following a hypocaloric diet on serum levels of adiponectin, inflammatory factors and oxidative stress parameters in obese and overweight patients with metabolic syndrome: a double-blind clinical trial

Public title

The effect of consuming the prepared cakes with acorn flour in patients with metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with metabolic syndrome Waist circumference greater than 102 cm in men and 88 cm in women Triglycerides equal to or greater than 150 mg/dL HDL less than or equal to 40 in men and less than or equal to 50 in women Blood pressure more than 130 to 85 mm Hg and blood sugar equal to or more than 100 mg/dL Stable body weight (weight change less than 3 kg in the last 3 months) Not participating in weight loss programs in the last 6 months

Exclusion criteria:

Diabetic patients receiving blood sugar lowering drugs and insulin History of alcohol consumption Smoking Pregnant and lactating women People with mental illnesses, cancer, thyroid, cardiovascular, lung, kidney, liver, eating disorders Taking drugs that affect appetite, body weight, calcium and vitamin D metabolism, and lipid metabolism or have an anti-inflammatory effect. Taking antioxidants or multivitamins and any type of food supplement Having lactose intolerance

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **66**

More than 1 sample in each individual

Number of samples in each individual: **2**

One sample was taken before the intervention and one after the intervention

Actual sample size reached: **63**

More than 1 sample in each individual

Actual sample size in each individual: **2**

One sample was taken before the intervention and one after the intervention

Randomization (investigator's opinion)

Randomized

Randomization description

After the 2-week run-in period, the patients will be randomly allocated to the intervention or placebo (control) group using the balanced block randomization method with a block size of 4. The treatment allocation will be performed using software-generated random numbers. Patients in the intervention group will consume two daily servings (2×30 g) of AC (n= 33) as snacks for 8 weeks a day; while those in the control group will be assigned to equal amounts of PC (n= 33) for the same period. The cakes will be prepared in the city of Shiraz. The intervention and control cakes will be equal in terms of shape, size, color, and taste. Also, both cakes will be prepared with identical packages and labeled as A or B, so that both study personnel and participants are unaware of the type of treatment.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Study participants, researchers, and laboratory personnel are blinded to group allocation until after the study. The designed placebo is completely similar to the intervention group in terms of color, smell, size and model. In order to blind the researcher, help is taken from a person who is not involved in the research process. The set of packs containing cakes prepared by a third party are coded as A and B.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shiraz University

Street address

Eram Blvd

City

shiraz

Province

Fars

Postal code

71946-84334

Approval date

2023-10-14, 1402/07/22

Ethics committee reference number

ir.us.rec.1402.009

Health conditions studied

1

Description of health condition studied

Metabolic syndrome

ICD-10 code

E88.81

ICD-10 code description

Metabolic syndrome

2

Description of health condition studied

Obesity due to excess calories

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Interleukin-6

Timepoint

Before and after the intervention

Method of measurement

ELISA (Enzyme-Linked Immunosorbent Assay) kit

2

Description

C reactive protein

Timepoint

Before and after the intervention

Method of measurement

ELISA (Enzyme-Linked Immunosorbent Assay) kit

Secondary outcomes

1

Description

malondialdehyde

Timepoint

before and after the intervention

Method of measurement

Thiobarbituric acid method

2

Description

total antioxidant capacity

Timepoint

before and after the intervention

Method of measurement

ELISA (Enzyme-linked immunosorbent assay) kit

3

Description

Adiponectin

Timepoint

before and after the intervention

Method of measurement

ELISA (Enzyme-linked immunosorbent assay) kit

Intervention groups

1

Description

Intervention group: the group that received the super-beneficial cake containing oak powder. The amount of calories in both oak and wheat cakes will be equal, so due to the higher calorie content of oak flour, 10 grams of sweetened oak flour should be used in preparing a cake containing oak flour, and 13.8 grams of wheat flour should be used in preparing a cake containing wheat flour. will be. Other ingredients of both cakes will be similar. A cake with an approximate weight of 30 grams will be produced and packaged in a standard way and will be considered as part of a snack to be consumed once a day by the patient.

Category

Treatment - Other

2

Description

Control group: The group receiving a cake containing wheat flour, a cake with an approximate weight of 30 grams will be produced and packaged in a standard way and will be considered as a part of the patient's snack to be consumed once a day.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Nutrition Clinic of Imam Reza Clinic

Full name of responsible person

hamed sadeghi-dehsahraei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty of Veterinary Medicine, Shiraz University

Full name of responsible person

mahboobeh ashrafi

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

No

Title of funding source

Faculty of Veterinary Medicine, Shiraz University

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Siavash Baba Jafari

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Khalili St

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mohsen.nut85@yahoo.com

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

No

Title of funding source

Shiraz university of medical sciences

Proportion provided by this source

50

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**

Faculty of Veterinary Medicine, Shiraz University

Full name of responsible person

hamed sadeghi-dehsahraei

Position

PhD student in biochemistry

Latest degree

Master

Other areas of specialty/work

Biochemistry

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Laboratory data can be published

When the data will become available and for how long

After studying

To whom data/document is available

For researchers and people working in industry

Under which criteria data/document could be used

Use of data in industry is allowed

From where data/document is obtainable

Hamed Sadeghi-dehsahraei - via email

sadeghidehsahraiihamed@yahoo.com

What processes are involved for a request to access data/document

The possibility of applying by email will be checked and answered within two weeks

Comments