Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Hamed Sadeghi-dehsahraei
Name of organization / entity
The University of Shiraz
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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 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
EIISA (Enzyme-linked immunosorbent assay) kit

3

Description
Adiponectin
Timepoint
before and after the intervention
Method of measurement
EIISA (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
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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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Postal code
71348-14336
Phone
+98 71 3612 2206
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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
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Person responsible for updating data

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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