Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Examining the Impact of Fast Diet and Calorie Deficit Diet on Emerging Adipokines Lipocalin 2, Irisin, and Inflammatory Markers among Women with Obesity/Overweight: a Randomized Clinical Trial

Protocol summary

Study aim

Examining the Impact of Fast Diet and Calorie Deficit Diet on Emerging Adipokines Lipocalin 2, Irisin, and Inflammatory Markers among Women with Obesity/Overweight

Design

This is a randomized, controlled, parallel-group trial. Participants will be stratified using stratified randomization based on age and BMI. Then using the random numbers table are assigned to one of the two groups intervention and control. Due to the dietary nature of the intervention, blinding is not feasible.However, Laboratory staff, the statistician, and the anthropometric assessor will be blinded to group allocation.The trial phase is not applicable.

Settings and conduct

Participants are selected from the Health Centers of Kashan University of Medical Sciences by convenient sampling. Participants are randomly assigned into two groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Women aged 18–50 years with BMI 25–40 kg/m², not following specific diets or using weight-loss medications/supplements, without chronic or psychological illnesses, and not pregnant or breastfeeding. Exclusion Criteria: Those with hypertension, diabetes, heart, or gastrointestinal diseases; smokers; individuals with eating disorders; or those non-adherent or lost to follow-up.

Intervention groups

Participants will adhere to a prescribed diet for 12 weeks, tailored to their group and daily energy requirements, which are calculated using the Mifflin equation. The FD diet (5:2 intermittent fasting protocol) involves two fasting days per week, during which participants consume only 25% of their recommended caloric intake, and five feeding days, where they consume 100% of their calculated daily energy requirements and follow these dietary plans for 12 weeks.

Main outcome variables

BMI, waist-hip ratio, visceral fat area, body fat percentage, Waist circumference, C-reactive protein , interleukin-1, MCP-1, irisin, lipocalin 2

General information

Reason for update

The study information was updated to clarify and complete the registered protocol details.

Acronym

IRCT registration information

IRCT registration number: **IRCT20220522054958N4**
Registration date: **2025-10-22, 1404/07/30**
Registration timing: **prospective**

Last update: **2026-10-06, 1405/07/14**
Update count: **1**

Registration date

2025-10-22, 1404/07/30

Registrant information

Name

Saeedeh Hosseini hooshiar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-03-21, 1405/01/01

Expected recruitment end date

2027-03-21, 1406/01/01

Actual recruitment start date

2026-03-21, 1405/01/01

Actual recruitment end date

2026-07-21, 1405/04/30

Trial completion date

empty

Scientific title

Examining the Impact of Fast Diet and Calorie Deficit Diet on Emerging Adipokines Lipocalin 2, Irisin, and Inflammatory Markers among Women with Obesity/Overweight: a Randomized Clinical Trial

Public title

The Impact of Fast Diet on Lipocalin 2, Irisin, and Inflammatory Markers

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The study will focus exclusively on women aged 18 to 50 to eliminate potential confounding factors related to sex-based differences in hormonal profiles, body composition, and metabolic responses to dietary interventions. This age range focuses on women during their reproductive years and excludes women undergoing significant menopausal transitions (as stated in the proposal's rationale). BMI (25-40 kg/m2): Participants will have a BMI ranging from 25 to 40 kg/m2. This BMI range ensures that all participants meet the criteria for overweight or obesity, as defined by the World Health Organization (WHO). Absence of Specific Diets/Weight Loss Medications/Supplements: Participants should not be following a specific diet or taking weight loss medications, and should not be consuming dietary supplements for weight loss. This ensures that the observed effects are attributable to the assigned dietary intervention (FD or CR) and not influenced by pre-existing dietary habits or pharmacological interventions. Absence of History of Chronic Illnesses: Absence of a history of chronic illnesses such as heart disease, hypertension, diabetes, and gastrointestinal disorders. Absence of Mental or Psychological Illnesses: Participants should be free from any mental or psychological illnesses. Not Pregnant or Breastfeeding: Participants should not be pregnant or breastfeeding. Participants are required to adhere to the prescribed caloric intake, with total caloric intake falling below 80% or exceeding 110% of the recommended amount.

Exclusion criteria:

Patients who may be diagnosed with hypertension, diabetes, heart disease, or gastrointestinal disorders during the study will be excluded to maintain the homogeneity of the study population and to prevent the confounding influence of newly developed health conditions on the study outcomes. Individuals who do not adhere to the prescribed caloric intake (defined as total caloric intake falling below 80% or exceeding 110% of the recommended amount) will be excluded due to the potential for this to compromise the integrity of the intervention and the validity of the results. Lost to Follow-Up/Unwilling to Continue: Participants who are lost to follow-up and are unwilling to continue the study will be excluded as they cannot provide complete data for analysis. Smoking has a profound impact on inflammation, oxidative stress, and metabolic function. To avoid confounding effects related to smoking, current smokers will be excluded. Individuals with a history of eating disorders (e.g., anorexia nervosa, bulimia nervosa) will be excluded due to the potential for these conditions to influence adherence to the dietary interventions and to confound the psychological and physiological outcomes of the study.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **47**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will undergo stratified randomization based on BMI (classified into two categories: 40 > BMI ≥ 30 and 30 > BMI ≥ 25) and age (classified into two categories: 50 > age ≥ 30 and 30 > age ≥ 18). Each subject will be ranked according to their age and BMI to ensure greater homogeneity between groups. Following this ranking, individuals will be assigned to either the control or intervention group using a random numbers table. Due to the nature of the intervention, blinding of participants to their group allocation is not feasible. An independent statistician, who remains blinded throughout the study, will generate the allocation sequences using a random numbers table.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

All participants will provide informed consent before entering the study. A physician and a trained nutritionist will thoroughly evaluate and inform the patients about the study's methodology, and written consent will be obtained. Demographic information will be collected using a questionnaire, and anthropometric measurements, such as BMI, waist-hip ratio, visceral fat area, body fat percentage, Waist circumference (WC), Hip circumference (HC), Mid-upper arm circumference (MUAC) and Forearm and calf circumference, will be recorded. The participants will then be randomized into either the intervention or control group using a random numbers table. Each individual will be assigned to either Group A, which follows the Fast Diet, or Group B, which

follows the Calorie Deficit Diet. Prior to the intervention, a 20 cc blood sample will be collected from each participant to measure biochemical, adipokines, and inflammatory indices.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Faculty of Medicine and Dentistry - Kashan University of Medical Sciences (Research Ethics Committee

Street address
5 km Qutb Ravandi Boulevard, Kashan University of Medical Sciences, Vice Chancellor for Research

City
Kashan

Province
Isfehan

Postal code
8715988141

Approval date
2025-05-04, 1404/02/14

Ethics committee reference number
IR.NIMAD.REC.1404.028

Health conditions studied

1

Description of health condition studied
Obesity or overweight

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Waist circumference

Timepoint
The beginning and end of the study

Method of measurement
using nonstretchable (flexible) tape measure

Secondary outcomes

1

Description
Mid-upper arm circumference

Timepoint
The beginning and end of the study

Method of measurement
Non-elastic tape measure

2

Description
Forearm circumference

Timepoint
The beginning and end of the study

Method of measurement
Non-elastic tape measure

3

Description
calf circumference

Timepoint
The beginning and end of the study

Method of measurement
Non-elastic tape measure

4

Description
total cholesterol

Timepoint
The beginning and end of the study

Method of measurement
Enzymatic method

5

Description
triglycerides

Timepoint
The beginning and end of the study

Method of measurement
Triglyceride oxidase

6

Description
high-density lipoprotein

Timepoint
The beginning and end of the study

Method of measurement
Fasting blood HDL cholesterol is measured in the laboratory.

7

Description
low-density lipoprotein

Timepoint
The beginning and end of the study

Method of measurement
Fasting blood LDL cholesterol is measured in the laboratory.

8

Description
fasting plasma glucose

Timepoint
The beginning and end of the study

Method of measurement
The fasting blood Glucose level determined in laboratory

9

Description
Body Mass Index
Timepoint
The beginning and end of the study
Method of measurement
Height: stadiometer, Weight: scale

10

Description
waist-hip ratio
Timepoint
The beginning and end of the study
Method of measurement
standard formula

11

Description
visceral fat area
Timepoint
The beginning and end of the study
Method of measurement
standard formula

12

Description
body fat percentage
Timepoint
The beginning and end of the study
Method of measurement
standard formula

13

Description
Hip circumference
Timepoint
The beginning and end of the study
Method of measurement
using nonstretchable (flexible) tape measure

14

Description
C-reactive protein
Timepoint
The beginning and end of the study
Method of measurement
Pars Azmoon commercial kit

15

Description
interleukin-1
Timepoint
The beginning and end of the study
Method of measurement
ELISA method

16

Description
Monocyte chemoattractant protein-1
Timepoint
The beginning and end of the study
Method of measurement
ELISA method

17

Description
irisin
Timepoint
The beginning and end of the study
Method of measurement
ELISA method

18

Description
lipocalin 2
Timepoint
The beginning and end of the study
Method of measurement
ELISA method

19

Description
Alanine Aminotransferase
Timepoint
The beginning and end of the study
Method of measurement
SGPT

20

Description
AST
Timepoint
The beginning and end of the study
Method of measurement
SGOT

21

Description
waist-to-hip ratio
Timepoint
The beginning and end of the study
Method of measurement
standard formula

Intervention groups

1

Description
Participants will adhere to a prescribed diet for 12 weeks, tailored to their group and daily energy requirements, which are calculated using the Mifflin equation. The FD diet (5:2 intermittent fasting protocol) involves two

fasting days per week, during which participants consume only 25% of their recommended caloric intake, and five feeding days, where they consume 100% of their calculated daily energy requirements across three main meals and three snacks. Feeding times are standardized: breakfast at 8:00, lunch at 13:00, dinner at 20:00, with snacks at 10:00, 16:00, and 22:00. The control group consumes 80% of their daily energy requirement with the same meal and snack schedule. Both groups follow these dietary plans for 12 weeks, with daily macronutrient distribution set at 55% carbohydrates, 30% fat, and 15% protein. Participants are monitored for any adverse effects, which are reported to the research staff, and no physical or psychological harm is anticipated from the study.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Kashan Health Centers

Full name of responsible person
Sadegh Jafarnejad

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Web page address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
National Institute for Medical Research Development(NIMAD)

Full name of responsible person
Sadegh Jafarnejad

Street address
کیلومتر پنجم بلوار قطب راوندی

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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
National Institute for Medical Research Development(NIMAD)

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
Kashan University of Medical Sciences

Full name of responsible person
Sadegh Jafarnejad

Position
Associate Professor

Latest degree
Medical doctor

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Sadegh Jafarnejad
Position
Associate Professor
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Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Saeedeh Hosseini Hooshiar
Position
PhD student
Latest degree
Master
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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
All data can be shared after making participants anonymous.
When the data will become available and for how long
Six months after publishing results, everything will be accessible.
To whom data/document is available
The data from this research will be accessible only to health researchers and those who are working in academic and scientific institutions
Under which criteria data/document could be used
With respect to ethical considerations, the data from this research can be used for other research purposes. It is also possible to conduct any statistical analyses. All these processes require correspondence and coordination.
From where data/document is obtainable
All applicants can contact Dr. Sadegh Jafarnejad through e-mail drsadegh2008@gmail.com
What processes are involved for a request to access data/document
Within 10 working days after correspondence or a phone call, your request will be answered and the data will be sent to a valid email submitted by the applicant.
Comments