Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

The effects of fasting mimicking diet versus low calorie diet on anthropometric measurements, body composition, insulin sensitivity and regulatory hormones of food intake on premenopausal obese women

Protocol summary

Study aim
To evaluate the effect of fasting mimicking diet versus a low-calorie diet on anthropometric measurements, insulin sensitivity, serum levels of leptin, ghrelin, and neuropeptide Y among premenopausal obese women.

Design
A total of 60 women with overweight or obesity based on the eligibility criteria will be included into the study. Participants will be randomly assigned to one of the two intervention studies. Each participant will be given a dedicated code.

Settings and conduct
It is a randomized controlled trial on women with obesity or overweight referred to Nutrition and Metabolic Diseases Center, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran.

Participants/Inclusion and exclusion criteria
Inclusion criteria: healthy premenopausal women aged 18-50 years BMI ranged 30-35 kg/m2 Exclusion criteria: use of any kinds of tobacco irregular menstrual cycle any symptoms of hyperandrogenism or PCOS use of any kind of contraceptive drugs any metabolic disorder which affect gluconeogenesis a medical history of heart disease considerable food allergies weight change of more than 3 kg in the last 3 months

Intervention groups
Participants will be assigned to the intervention group provided with a fasting mimicking diet for 5 days of a month and 25 days of usual dietary intake. and the placebo with a low calorie diet.

Main outcome variables
body weight; fat mass; fat free mass; serum glucose; insulin; leptin; adiponectin; neuropeptide Y

General information

Reason for update
updating the steps of the project process

Acronym

IRCT registration information
IRCT registration number: **IRCT20190717044244N1**
Registration date: **2019-08-19, 1398/05/28**
Registration timing: **prospective**

Last update: **2020-04-06, 1399/01/18**
Update count: **1**

Registration date
2019-08-19, 1398/05/28

Registrant information

Name
mehdi sadeghian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3373 8253

Email address
mehdisad69@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-21, 1398/05/30

Expected recruitment end date
2020-02-20, 1398/12/01

Actual recruitment start date
2019-08-24, 1398/06/02

Actual recruitment end date
2020-02-20, 1398/12/01

Trial completion date
2020-03-05, 1398/12/15

Scientific title

The effects of fasting mimicking diet versus low calorie diet on anthropometric measurements, body composition, insulin sensitivity and regulatory hormones of food intake on premenopausal obese women

Public title

Fasting mimicking diet compared with low calorie diet among premenopausal obese women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

healthy women aged 18-50 years BMI ranged from 30 to 35 not to use any tobacco regular menstrual cycle not to have symptoms of hyperandrogenism or PCOS not to use contraceptive drugs negative pregnancy test not having metabolic disorder affecting gluconeogenesis not having medical history of heart diseases not having considerable food allergies weight change less than 3 kg in the last 3 months not having psychotic disorder affecting the patients' adherence

Exclusion criteria:

not to have adherence to the diet unwilling to continue the trial

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will randomly assigned to the 2 groups. Every patient will receive a code number. The the codes were written on concealed letters and will be chosen by a second person and assign randomly to one of the study groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

As the study is a diet intervention trial, it is not possible to blind the personnel. However, study personnel involved in data collection and specimen analysis will be blinded to group assignments.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

golestan

City

ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2019-03-12, 1397/12/21

Ethics committee reference number

IR.AJUMS.REC.1398.281

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

body weight

Timepoint

Body weight will be measured just before the inclusion in the trial and at the end of the intervention (after 2 months).

Method of measurement

digital scale

Secondary outcomes

1

Description

body fat mass

Timepoint

Body fat mass will be measured just before the inclusion in the trial and at the end of the intervention (after 2 months).

Method of measurement

Body composition analyzer

2

Description

fat free mass

Timepoint
Fat free mass will be measured just before the inclusion in the trial and at the end of the intervention (after 2 months).
Method of measurement
Body composition analyzer

3

Description
serum glucose
Timepoint
Serum glucose will be measured just before the inclusion in the trial and at the end of the intervention (after 2 months).
Method of measurement
enzymatic methods

4

Description
Serum insulin
Timepoint
Serum glucose will be measured just before the inclusion in the trial and at the end of the intervention (after 2 months).
Method of measurement
ELISA

5

Description
ghrelin
Timepoint
Serum ghrelin will be measured just before the inclusion in the trial and at the end of the intervention (after 2 months).
Method of measurement
ELISA

6

Description
Leptin
Timepoint
Serum leptin will be measured just before the inclusion in the trial and at the end of the intervention (after 2 months).
Method of measurement
ELISA

7

Description
Neuropeptide Y
Timepoint
Serum neuropeptide Y will be measured just before the inclusion in the trial and at the end of the intervention (after 2 months).
Method of measurement
ELISA

8

Description
Waist circumference
Timepoint
Waist circumference will be measured just before the inclusion in the trial and at the end of the intervention (after 2 months).
Method of measurement
Meter

Intervention groups

1

Description
Intervention group: fasting mimicking diet will be administered during the first 5 days of a month (In total, 2 five-days cycles for 2 months). Fasting mimicking diet is a plant-based diet providing both micro- and macro-nutrients to decrease side-effects of fasting. It consists of a total of 1099 kcal (11% protein, 46% fat, 43% carbohydrate) in the first day, and a total of 717 kcal (9% protein, 44% fat, 47% carbohydrate) in the 4 following days. This will be provided by semi-prepared soups form Mahram and Elit companies. Also, a multi vitamin mineral from Supplex company and an omega3 supplement from Eurovital company will be provided during the 5 days of the cycle. Participants should continue their usual diet during the other 25 days of a month.
Category
Lifestyle

2

Description
Control group: Calorie deficit of 500 kcal for 2 months. the diet will be a Mediterranean diet with 30-35% fat, 20% protein, and 45-50% carbohydrate (mostly from whole grains) emphasizing on vegetables, fruits, cereals, fish, poultry, nuts, olive oil, and limiting processed meats, red meats, and sweets.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Nutrition and Metabolic Diseases Research Center, Ahvaz Jundishapur University Of Medical Sciences,
Full name of responsible person
Ahmad Zarejavid
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Email
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Grant name
Grant code / Reference number
IR.AJUMS.REC.1398.281
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
Mehdi Sadeghian
Position
Ph.D. student
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
No - There is not 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
Yes - There is 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
Title and more details about the data/document
Only some data on the primary outcome can be published upon request, If we have permission from the Ethics Committee.
When the data will become available and for how long
undecided
To whom data/document is available
undecided
Under which criteria data/document could be used
undecided
From where data/document is obtainable
mehdisad69@gmail.com
What processes are involved for a request to access data/document
After permission from ethics committee. It may take at last 1 week.
Comments