# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Oct 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)

**Phone**
+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
**Street address**
golestan
**City**
Ahvaz
**Province**
Khouzestan

**Postal code**
61357-15794
**Phone**
+98 61 3373 8253
**Email**
mehdisad69@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Ahmad Zarejavid
**Street address**
Golestan
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
61357-15794
**Phone**
+98 61 3373 8253
**Email**
mehdisad69@gmail.com
**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**
Ph.D.
**Other areas of specialty/work**
Nutrition
**Street address**
Golestan
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
61357-15794
**Phone**
+98 61 3373 8253
**Email**
mehdisad69@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Mehdi Sadeghian
**Position**
Ph.D. Candidate
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nutrition
**Street address**
Golestan
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
61357-15794
**Phone**
+98 61 3373 8253
**Email**
mehdisad69@gmail.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Mehdi Sadeghian
**Position**
Ph.D. Candidate
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nutrition
**Street address**
Golestan
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
61357-15794
**Phone**
+98 61 3373 8253

**Email**
mehdisad69@gmail.com

## 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**