

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation and comparison of the effect of Alternate Day Fasting and Low Calorie Diet on basal metabolic rate and body composition in overweight and obese individuals

Protocol summary

Study aim

1) Comparison of the situation of body composition and basal metabolic rate in two groups before and after the study. 2) Comparison of change in glucose, serum insulin and lipid profile in two groups before and after the intervention.

Design

This clinical trial with two intervention groups was performed in parallel, without randomized and blinded, on 100 patients.

Settings and conduct

Place of study at Imam Reza Hospital in Mashhad. Both groups were measured and evaluated before and after the study by indirect calorimetry, the metabolic energy of the base and with the bio-impedance analysis apparatus of their body composition. During a weekly study, a 24-hours recall is taken once a week.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Male and female both sexes 2) Age between 18 and 40 years 3) BMI ≥ 25 and less than 40 4) weight stability for 3 months before study 5) Have no history of gastric surgery 6) Have not consumed medicines for weight loss in last 6 months 7) Based on the acknowledgment of the participants, no history of diabetes, hypertension, cardiovascular diseases, liver and kidney disorders, thyroid and lipid dysfunction or do not consume drugs related to these diseases Non-entering study criteria: 1) pregnancy and lactation 2) suffering from a diseases that can eliminate the possibility of a low calorie diet and fasting diet

Intervention groups

We have two groups in this study. The first group is the Alternate Day Fasting that will receive 24 hours a very low calorie diet (25 to 30 % of total daily energy) and 24 hours later an isocaloric diet. The second group is a Low Calorie Diet that will received a normal weight loss diet. (25% decrease in total daily energy). The duration in two

groups was 8 weeks.

Main outcome variables

Body composition, Basal metabolic rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200614047765N1**

Registration date: **2020-06-27, 1399/04/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-27, 1399/04/07**

Update count: **0**

Registration date

2020-06-27, 1399/04/07

Registrant information

Name

Afrouz Pishbin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3830 6808

Email address

pishbina961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the effect of Alternate Day Fasting and Low Calorie Diet on basal metabolic rate and body composition in overweight and obese individuals

Public title

Evaluation and comparison of the effect of Alternate Day Fasting and Low Calorie Diet on basal metabolic rate and body composition in overweight and obese individuals

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 and 45 years old BMI ≥ 25 and less than 40 Weight stability for 3 months before the start of study (no more than 3kg decreased or increased weight) Have no history of gastric surgery In the last six months, they have not used medicine to reduce weight Based on the acknowledgement of participants, diabetes, hypertension, cardiovascular disease, liver and kidney disorders and lipid disorders and thyroid problems are not, or do not consume drugs related to these diseases

Exclusion criteria:

The diseases that eliminate the possibility of a low-caloric or fasting diet in an individual Pregnancy and lactation

AgeFrom **18 years** old to **45 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **100****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Mashhad University of Medical Sciences

Street address

No. 145, 12 Hamedei alley., Amirkabir Blvd., Shiraz Town

City

Shiraz

Province

Fars

Postal code

7175715973

Approval date

2019-01-01, 1397/10/11

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.730

Health conditions studied**1****Description of health condition studied**

Overweight and obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes**1****Description**

Body composition

Timepoint

Before the beginning of the study and after the end of eighth week

Method of measurement

Inbody 770 Body Composition Analyzer

2**Description**

Basal Metabolic Rate

Timepoint

Before the beginning of the study and after the end of eighth week

Method of measurement

Indirect calorimetry using Metalyzer 3B-R3 (German Cortex company)

Secondary outcomes**1****Description**

Fasting blood glucose

Timepoint

Before the study and after the end of the eighth week

Method of measurement

Blood test

2

Description

Serum insulin

Timepoint

Before the study and after the end of the eighth week

Method of measurement

Blood test

3

Description

Lipid profile

Timepoint

Before the study and after the end of the eighth week

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group: Get the Alternate Day Fasting diet in this group. During the 24 hours a very low calorie diet (25 to 30% of total daily energy) is received and 24 hours later they receive an isocaloric diet. The process continues intermittently for 8 weeks.

Category

Treatment - Other

2

Description

Control group: Receiving Low Calorie Diet in this group, they receive a normal weight loss diet (25% reduction of total daily energy) every day. The study period in this group is 8 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Mohsen Nematy

Street address

East door of Ferdowsi University, Public Relation
Department of the University

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3882 7034

Email

pishbina961@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Nematy

Street address

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Department of University

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Afroz Pishbin

Position

M.Sc Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Afrouz Pishbin

Position

M.Sc Student

Latest degree

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All information and data obtained will be published as an article

When the data will become available and for how long

Six month after the article was published

To whom data/document is available

All people who need information

Under which criteria data/document could be used

All people who need information

From where data/document is obtainable

pishbina961@mums.ac.ir

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

The request is sent with the following email in the first opportunity to email data file

Comments