Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of modified Alternate-Day Fasting (ADF) in contrast with Calorie Restriction (CR) on anthropometric indices, glycemic markers and cardiovascular risk factors in metabolic syndrome patients.

Protocol summary

Study aim

The purpose of the present study was to investigate and compare the impact of Modified Alternate- Day Fasting versus daily Calorie Restriction on anthropometric indices, glycemic markers, and cardiovascular risk factors in patients with metabolic syndrome.

Design

The clinical randomized trial, sham-controlled clinical trial with parallel groups

Settings and conduct

Subjects were recruited from the Sediqe- Tahere Heart Center. after classification and matched according to age, sex, and BMI, these subjects were randomly divided into two groups. a group of subjects received Modified ADF and another group received Calorie Restriction for 8 weeks. At the beginning and the end of the study, outcomes were measured. The energy requirement of each person was calculated by Mifflin equation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with metabolic syndrome, high BMI, no weight changes more and less than 5% for 3 months, no fasting for 3 months, Exclusion criteria: smoking, history of the disease, use of the desired drugs

Intervention groups

In Modified ADF group, subjects consumed very low-calorie diet (75% energy restriction) during the 3 fast days (Saturday, Monday, Wednesday) and then ate the diet that providing 100% of their energy needs on each feed day (3 days a week). In Friday subjects consumed ad libitum without limitation. in Calorie Restriction group, subjects consumed 75% energy needs in each day.

Main outcome variables

Body weight, BMI, systolic blood pressure, diastolic blood pressure, fasting blood sugar, total cholesterol, LDL cholesterol, HDL cholesterol, triglyceride, body fat mass, fat-free mass, fasting insulin, HOMA-IR

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150909023957N8**
Registration date: **2019-01-23, 1397/11/03**
Registration timing: **retrospective**

Last update: **2019-01-23, 1397/11/03**
Update count: **0**

Registration date

2019-01-23, 1397/11/03

Registrant information

Name

Sayyed Morteza Safavi

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan university of medical science

Expected recruitment start date

2017-07-06, 1396/04/15

Expected recruitment end date

2017-09-06, 1396/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of modified Alternate-Day Fasting (ADF) in contrast with Calorie Restriction (CR) on anthropometric indices, glycemic markers and cardiovascular risk factors in metabolic syndrome patients.

Public title
Effect of low-calorie diets on anthropometric indices, glycemic markers and cardiovascular risk factors in metabolic syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with Metabolic Syndrome Age 25-60 years 25 ≤BMI ≤40 kg/m2 Body weight more than 5 kg has not changed during the last 3 months. No fasting for 3 months prior to the beginning of the study People who are willing to cooperate and answer questions and conduct their tests after explaining the work.

Exclusion criteria:
Smoker History of cardiovascular, pulmonary, renal, thyroid disorders, digestive and liver problems such as hepatitis and ... Follow a special diet Severe physical activity People who have been using drugs that have an effect on weight loss, lipid or glucose metabolism over the past 6 months.

Age
From **25 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
All participants were stratified for body mass index (BMI), age and sex, and were randomly assigned to ADF or CR group for 8 weeks. Randomization was performed using by random- generation software.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan university of medical sciences

Street address
isfahan, hezar jerib street, Isfahan univercity of medical science

City
Isfahan

Province
Isfehan

Postal code
81745319

Approval date
2015-06-05, 1394/03/15

Ethics committee reference number
IR.MUI.REC.1394.3.891

Health conditions studied

1

Description of health condition studied
metabolic syndrome disease

ICD-10 code
E88.81

ICD-10 code description
Metabolic syndrome

Primary outcomes

1

Description
Body weight and body composition analysis

Timepoint
Two times, before and after dietary intervention

Method of measurement
In light clothing, standing without shoes and hose on metal foot- plates while holding the handles of the bio-impedance analyzer (BIA; BC-418, Tanita Europe, Amsterdam, NL)

2

Description
BMI

Timepoint
Two times, before and after dietary intervention

Method of measurement
BMI was calculated as the weight in kilograms divided by the square of the height in meters (kg/m2)

3

Description
Waist circumference

Timepoint

Two times, before and after dietary intervention

Method of measurement

Waist circumference was measured by a flexible tape to the nearest 0.1 cm, in standing subject at the midway between the lower costal margin of the last palpable rib and the top of the iliac crest during a period of expiration.

4

Description

Triglyceride (TG)

Timepoint

Two times, before and after dietary intervention

Method of measurement

Plasma TG concentration was measured glycerol phosphate oxidase/peroxidase method.

5

Description

Total cholesterol

Timepoint

Two times, before and after dietary intervention

Method of measurement

Plasma total cholesterol was measured in duplicate using cholesterol oxidase/peroxidase.

6

Description

HDL cholesterol

Timepoint

Two times, before and after dietary intervention

Method of measurement

Plasma HDL-C were measured Detergent oxidase/peroxidase methods.

7

Description

LDL cholesterol

Timepoint

Two times, before and after dietary intervention

Method of measurement

LDL-C concentration was calculated using the Friedwald equation (LDL= total cholesterol – TAG/ 2.18 – HDL).

8

Description

Fasting blood sugar

Timepoint

Two times, before and after dietary intervention

Method of measurement

Fasting plasma glucose concentrations were measured using auto-analyzer (glucose oxidase/peroxidase).

9

Description

Plasma insulin

Timepoint

Two times, before and after dietary intervention

Method of measurement

Plasma insulin levels were measured by Elisa method.

10

Description

HOMA-IR

Timepoint

Two times, before and after dietary intervention

Method of measurement

fasting glucose (mmol/L) * fasting insulin (µU/L)/ 22.5.

Secondary outcomes

empty

Intervention groups

1

Description

During 8-week ADF period, subjects consumed very low calorie diet (75% energy restriction) during the 3 fast days (Saturday, Monday, Wednesday) and then ate diet that providing 100% of their energy needs on each feed day (3 days a week). In Friday subjects consume ad libitum without limitation. ADF subjects were provided with meals on each fast day (ranging from 400- 600 kcal), and consumed ad libitum at home on feed day. The feed and fast days began at midnight each day, and all fast day meals were consumed between 12.00 pm and 2.00 pm to ensure that each subject was undergoing the same duration of fasting. all food prepared in the home. Subjects were permitted to consume calorie- free foods (such as water, green tea, coffee without sugar (< 400 mg caffeine per day), non-starchy vegetable (such as lettuce, cucumber, green leaf, tomato) and sugar free gums on the fast day and were encouraged to drink plenty of water.

Category

Lifestyle

2

Description

Control group: In Calorie Restriction group, subjects consumed 75% energy needs in each day for 8 weeks and includes 3 main meals and 2 snacks. All subjects in two groups were required to prepare all of their meals at home. The baseline energy requirements for the subjects were assessed by Mifflin equation. Daily dietary carbohydrate, fat and protein accounted for 52, 30 and 18% of ingested energy, respectively.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Cardiovascular Research Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Vice Chancellor for Research, Isfahan 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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
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arefe parvaresh
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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