Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Effects of Intermittent Calorie Restriction on Inflammatory Markers in Overweight and Obese Adults

Protocol summary

Study aim
The effect of two types of low calorie diets on plasma levels of inflammatory factors in overweight or obese people with hypertriglyceridemia

Design
A randomized clinical trial with two-arm parallel-group, one will be put in an intermittent VLCD and the other group will have continuous calorie restriction, will start with a sample size of 80 in April 2020 and will be continued until June 2020.

Settings and conduct
Eighty obese or overweight subjects who volunteered by the advertisements will be assigned to the study groups and will be observed at the Nutrition and diet therapy Clinic of Shahid-Beheshti University of Medical Sciences. These individuals are divided into two groups. 1. intermittent calorie-restriction diet, or 2. continuous calorie restriction. At baseline and after two months of the diet, each person's plasma inflammatory factors will be measured and compared.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1- Body mass index more than 25 2- Age 18-60 years 3- non-smoker 4-Haven't has been under any diet at least 3 months before participating in the study 5-Not starting any new exercise program or changing the previous exercise while in the study Exclusion Criteria: 1-Chronic kidney disease stage 3-5 2-Consuming Insulin or Insulin-inducing drugs 3-Consuming Omega 3 supplement 4-A history of cholecystitis 5- Heart arrhythmia

Intervention groups
Group1: Participants will have a very low-calorie diet (VLCD) 3 days a week (alternate-days), which provides only 30% of the individual's energy requirement for weight maintenance. However, they will receive 100% of their daily need for energy for the remaining 4 days of the week. Group 2: Participants will follow a classic calorie-restricted diet with a 30% reduction in daily energy requirement for weight maintenance.

Main outcome variables
Plasma C-Reactive Protein

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160702028742N7**
Registration date: **2020-03-19, 1398/12/29**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-19, 1398/12/29**
Update count: **0**

Registration date
2020-03-19, 1398/12/29

Registrant information
Name
Javad Nasrollahzadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-04-12, 1398/01/23
Expected recruitment end date
2020-06-20, 1399/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of Intermittent Calorie Restriction on Inflammatory Markers in Overweight and Obese Adults

Public title
Effects of Intermittent Calorie Restriction on Inflammatory Markers

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Body Mass Index over than 25 kg/m2 Willing to participate in the study Age between 18 to 60 years non smoker haven't been under any diet at least 3 months before participating in the study not starting any new exercise program or changing the previous exercise while in the study

Exclusion criteria:
chronic kidney disease stage 3-5 consuming Insulin or Insulin-inducing drugs. consuming omega 3 supplement a history of cholecystitis Heart arrhythmia

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization tool is a sealed envelope. Stratified block randomization will be employed to assign subjects to each of the two groups. Stratification subdivides patients into those with diabetes or without diabetes and in each stratum, blocks of size 4 (two intervention and two control) will be defined and then the patients within each block will be assigned to intervention receiving intermittent calorie-restriction diet (intervention group) or continuous calorie restriction diet (comparison group).

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 Shahid Beheshti University of Medical Sciences

Street address
No. 46, West Arghavan Ave., Farahzadi Blvd., Qods Town

City
Tehran

Province
Tehran

Postal code
1981619573

Approval date
2019-06-19, 1398/03/29

Ethics committee reference number
IR.SBMU.NNFTRI.REC.1398.019

Health conditions studied

1

Description of health condition studied
Overweight and obesity

ICD-10 code

ICD-10 code description
Overweight and obesity

2

Description of health condition studied
overweight and obesity

ICD-10 code

ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Plasma C-reactive protein (CRP)

Timepoint
Baseline and the end of the study

Method of measurement
Turbidometric method using kits

2

Description
interleukin 6

Timepoint
Baseline and the end of the study

Method of measurement
ELISA

3

Description
interleukin 10

Timepoint

Baseline and the end of the study

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants in the group will be on a very low-calorie diet (30% of the individual's energy requirement for weight maintenance) for 3 days throughout the week, and on other days they will have the calorie needed to maintain weight (100% of their daily need for energy).

Category

Treatment - Other

2

Description

Control group: Participants in this group will have a daily calorie restricted diet (calorie deficient equivalent to a 30% of one's energy requirement for weight maintenance).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Nutrition and Diet therapy Clinic of Faculty of Nutrition Sciences and Food Technology, Shahid Behes

Full name of responsible person

Mahsa Maroofi

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

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No. 46, Hafezi street, Farahzadi blvd, Qods Town, Tehran

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahsa Maroofi

Position

Master of science student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Javad Nasrollahzadeh

Position
Assistant Professor

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Ph.D.

Other areas of specialty/work
Nutrition

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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available