

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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)

Phone

+98 21 2236 0656

Email address

jnasrolah@razi.ac.ir

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 titleEffects 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 descriptionThe 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

Street address

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

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Javad Nasrollahzadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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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