

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of weight loss diet with and without statin medication on plasma lipid profile

Protocol summary

Study aim

The effect of a balanced low-calorie diet on plasma lipid and lipoprotein concentrations in two groups of obese or overweight individuals, one group of non-statin users, and the other group of statin-treated groups will be examined.

Design

The study has a parallel design.

Settings and conduct

Among the volunteers with inclusion criteria, based on whether the volunteers are being treated with statin drugs or not, they are assigned to one of the two groups: 1- treated with statins and 2- not using statins. People in both groups will be put on the low-calorie diet for 2 months.

Participants/Inclusion and exclusion criteria

Inclusion: BMI > 25 kg/m² No weight change of more than 1-2 kg in the past month LDL-C less than 130 mg/dL Taking statins for more than 2 months (participants in the statin group) Exclusion: Chronic kidney disease (Cr > 1.4 mg / dl), cancer, autoimmune or inflammatory diseases treated with corticosteroids Pregnancy and lactation Regular use of garlic pills, omega-3 supplements, or flaxseed Changes in medications during the study period

Intervention groups

1. Low calorie diet in people who do not use lipid lowering drugs 2. Low calorie diet in people who are on statin medications

Main outcome variables

Plasma total Cholesterol to HDL-cholesterol ratio

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160702028742N10**

Registration date: **2021-01-30, 1399/11/11**

Registration timing: **prospective**

Last update: **2021-01-30, 1399/11/11**

Update count: **0**

Registration date

2021-01-30, 1399/11/11

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

2021-02-06, 1399/11/18

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of weight loss diet with and without statin medication on plasma lipid profile

Public title

Effects of weight loss with blood lipid-lowering medication on blood lipid concentration

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
BMI>25 kg/m² No weight change of more than 1-2 kg in the past month LDL-C less than 130 mg/dL Taking statins for more than 2 months (participants in the statin group)

Exclusion criteria:
chronic chronic kidney disease (Cr> 1.4 mg / dl), cancer, autoimmune or inflammatory diseases treated with corticosteroids Pregnancy and lactation Regular use of garlic pills, omega-3 supplements, or flaxseed Changes in medications during the study period

Age
From **40 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

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

National Nutrition and Food Technology Research
Institute Ethic Committee

Street address

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

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2021-01-10, 1399/10/21

Ethics committee reference number

IR.SBMU.nnftri.Rec.1399.056

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

Plasma total cholesterol to HDL-cholesterol ratio

Timepoint

Baseline and after 2 months

Method of measurement

Enzymatic

Secondary outcomes

1

Description

Plasma LDL-C

Timepoint

Baseline and after 2 months

Method of measurement

Enzymatic

2

Description

Plasma TG

Timepoint

Baseline and after 2 months

Method of measurement

Enzymatic

3

Description

CRP

Timepoint

Baseline and after 2 months

Method of measurement

Turbidometry

4

Description

IL-6

Timepoint

Baseline and after 2 months

Method of measurement

ELISA

5

Description

Plasminogen activator inhibitor-1

Timepoint

Baseline and after 2 months

Method of measurement

ELISA

6

Description

Apolipoprotein B

Timepoint

Baseline and after 2 months

Method of measurement

Turbidometry

Intervention groups

1

Description

Intervention group: Overweight or obese people who have been regularly taking statins before starting the study are put on a healthy low-calorie diet.

Category

Lifestyle

2

Description

Control group: Overweight or obese people who have not been taking statins before starting the study are put on a healthy low-calorie diet.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Outpatient Diet Therapy Clinic

Full name of responsible person

Javad Nasrollahzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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

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nnftri_food@yahoo.com

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

Javad Nasrollahzadeh

Position

Assistant professor

Latest degree

Ph.D.

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

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Javand Nasrollahzadeh

Position

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Person responsible for updating data

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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

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

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