Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Oct 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 moths

Method of measurement

Enzymatic

2

Description

Plasma TG

Timepoint

Baseline and after 2 moths

Method of measurement

Enzymatic

3

Description

CRP

Timepoint

Baseline and after 2 moths

Method of measurement

Turbidometry

4

Description

IL-6

Timepoint

Baseline and after 2 moths

Method of measurement

ELISA

5

Description
Plasminogen activator inhibitor-1
Timepoint
Baseline and after 2 moths
Method of measurement
ELISA

6

Description
Apolipoprotein B
Timepoint
Baseline and after 2 moths
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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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
Afshin Zarghi
Street address
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

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Latest degree

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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