

# 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/m<sup>2</sup> 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/m<sup>2</sup> 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

##### Street address

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

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##### Province

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##### Postal code

1981619573

##### Phone

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##### Email

jnasrollahzadeh@gmail.com

## 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,

##### City

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##### Province

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##### Phone

+98 21 2236 0658

##### Email

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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jnasrollahzadeh@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Javand Nasrollahzadeh

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Javand Nasrollahzadeh

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Assistant professor

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**Email**

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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