

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Evaluate the performance of three different diets (low calorie, balanced, low calorie - low carb and low calories - low fat) on high-sensitivity c-reactive protein and lipid profile in overweight adults aged 25-60 years

Protocol summary

Summary

purpose of study: Evaluation of high sensitive c-reactive protein and lipid profile changes after using three kind of diet in overweight people who referred to Shiraz healthy heart house Design of study: Randomized clinical trial (RCT), single blind, single-center Study Population: People are overweight ($BMI \geq 25$) in order to assess their health status referring to Shiraz Healthy Heart Home. Inclusion criteria: a certificate of age from 25 to 60 years; People with overweight ($BMI \geq 25$). Exclusion criteria: Changes in diet; Hospitalization; time of sampling. sample size: 120 people. Interventions: group A: low calorie-balanced, group B: low calorie-low carbohydrate, group C: low calorie-low fat. Duration of intervention: 12 weeks. Outcomes of the study: A new model for nutritional intervention to reduce weight, reduce high-sensitivity C-reactive protein levels and improves lipid profile

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013100614914N1**

Registration date: **2014-09-09, 1393/06/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-09-09, 1393/06/18

Registrant information

Name

Afshin Lazarjani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1231 5975

Email address

lazarjani@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Council of Shiraz University of Medical Sciences

Expected recruitment start date

2014-03-06, 1392/12/15

Expected recruitment end date

2014-06-05, 1393/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluate the performance of three different diets (low calorie, balanced, low calorie - low carb and low calories - low fat) on high-sensitivity c-reactive protein and lipid profile in overweight adults aged 25-60 years

Public title

Evaluate the performance of three different diets (low calorie, balanced, low calorie - low carb and low calories - low fat) on high-sensitivity c-reactive protein and lipid profile in overweight individuals

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Individuals must complete a consent form to participate in the project; a certificate of age from 25 to 60 years; no use of lipid-lowering medications; no history of kidney disease; liver disease;

heart disease; thyroid disorders, diabetes; and rheumatologic diseases. Exclusion criteria: those who did not fill out a consent form or were withdrawn from the plan; Changes in diet; changes in daily physical activity; pregnancy; lactation or use of oral contraceptives; Conditions that require patients to lipid-lowering drugs; Alcohol consumption; Non-fasting blood samples; Hospitalization; time of sampling; Acute infectious diseases.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single 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 Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand St, Shiraz

City

Shiraz

Postal code

7134814336

Approval date

2013-08-18, 1392/05/27

Ethics committee reference number

CT-P-92-4698

Health conditions studied**1****Description of health condition studied**

Overweight

ICD-10 code

E66.9

ICD-10 code description

Overweight

Primary outcomes**1****Description**

High-sensitivity c-reactive protein

Timepoint

Before the experiment, 12 weeks after the intervention.

Method of measurement

biochemical measurements on blood sample

2**Description**

Serum triglycerides

Timepoint

Before the experiment, 12 weeks after the intervention

Method of measurement

biochemical measurements on blood sample

3**Description**

High-density lipoprotein

Timepoint

Before the experiment, 12 weeks after the intervention.

Method of measurement

biochemical measurements on blood sample

4**Description**

low-density lipoprotein

Timepoint

Before the experiment, 12 weeks after the intervention.

Method of measurement

biochemical measurements on blood sample

5**Description**

total cholesterol

Timepoint

Before the experiment, 12 weeks after the intervention.

Method of measurement

biochemical measurements on blood sample

Secondary outcomes**1****Description**

Body Mass Index

Timepoint

Before the experiment, 12 weeks after the intervention.

Method of measurement

Calculated according to the formula

2

Description

Weight

Timepoint

Before the experiment, 12 weeks after the intervention.

Method of measurement

Electronic Scales

Intervention groups

1

Description

group A: low calorie-balanced:50-55% carbohydrate,12-15% protein,25-30% fat,500 kcal less than the daily intake for a period of three months from baseline

Category

Lifestyle

2

Description

group B: low calorie-low carbohydrate:35-40% carbohydrate,25-30% protein,<40% fat,500 kcal less than the daily intake for a period of three months from baseline

Category

Lifestyle

3

Description

group C: low calorie-balanced:45-60% carbohydrate,15-20% protein,<20% fat,500 kcal less than the daily intake for a period of three months from baseline

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiovascular Research Center of Shiraz University of Medical Sciences

Full name of responsible person

Afshin Lazarjani

Street address

Cardiovascular Research Center, Shahid Faghihi Hospital, Zand Blvd, Shiraz

City

Shiraz

2

Recruitment center

Name of recruitment center

Shiraz Healthy Heart Home

Full name of responsible person

Afshin Lazarjani

Street address

Shiraz, Modares Blvd, opposite St Fazilat, Center for Healthy Heart Home

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Shahdad khosropanah

Street address

Cardiovascular Research center, Shahid Faghihi Hospital, Zand Blvd, Shiraz

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Shahdad Khosropanah

Position

Associate Professor of Cardiology

Other areas of specialty/work

Street address

Shiraz University of Medical Sciences, Zand St, Shiraz

City

Shiraz

Postal code

Phone

+98 71 1229 7767

Fax

Email

shahdad44@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Science

Full name of responsible person

Shahdad Khosropanah

Position

Associate Professor of Cardiology

Other areas of specialty/work

Street address

Cardiovascular Research center, Shahid Faghihi
Hospital, Zand Blvd, Shiraz

City

Shiraz

Postal code

Phone

+98 71 1229 7776

Fax

Email

shahdad44@yahoo.com

Web page address

Afshin Lazrjani

Position

Resident of Cardiology

Other areas of specialty/work

Street address

Shiraz University of Medical Sciences, Zand St, Shiraz

City

Shiraz

Postal code

Phone

00

Fax

Email

lazarjani@sums.ac.ir; afshin.lazarjani@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person