

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of olive oil rich diet consumption on serum omentin concentration in overweight women

Protocol summary

Summary

The purpose of this research is to study the effect of olive oil rich diet consumption on serum omentin concentration in overweight women. The research is a randomized clinical trial (cross-over). Inclusion Criteria: females age between 20-50-year, BMI between 25-29/9, Exclusion criteria: pregnancy, breast feeding, history of coronary artery disease, diabetes, metabolic diseases, arthritis, lupus, GI diseases, hypertension, any kind of infection, trauma, thyroid diseases, history of using drugs, such as (anti hypertension, anti hyperlipidemia, anti-inflammation, anti diabetic agents, drugs for weight reduction, OCP, corticosteroids). 16 healthy females will participate in the study and will be randomly divided into two groups. Group 1 will receive a diet with energy restriction (-500 kcal), 51% carbohydrate, 15% protein, 34% fat, 16% SFA, 10% PUFA, 8% MUFA. Group 2 will receive a diet with energy restriction (-500 kcal) and rich in extra virgin olive oil with composition: 51% carbohydrate, 15% protein, 34% fat, 8% SFA, 10% PUFA, 16% MUFA. The subjects in each group will follow the diet for six weeks and after two weeks for wash out period the two groups will change place with regard the diet they are receiving. They will follow the new diet for another six weeks. At the beginning and the end of each phase a blood sample (10 cc) will be collected and anthropometric indices will be measured. In addition, a 24-h recall and a physical activity questionnaire will be completed by subjects every other week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812223550N1**

Registration date: **2009-09-23, 1388/07/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-09-23, 1388/07/01

Registrant information

Name

Akram Kabiry

Name of organization / entity

Tehran university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 33 5527 1917

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Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences

Expected recruitment start date

2009-09-23, 1388/07/01

Expected recruitment end date

2009-11-06, 1388/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of olive oil rich diet consumption on serum omentin concentration in overweight women

Public title

The effect of olive oil rich diet consumption on serum omentin concentration

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion Criteria: married women age: 20-50-year, BMI between 25-29/9, absence of clinical signs or symptoms of coronary artery disease, diabetes, metabolic diseases, arthritis, lupus, GI diseases, hypertension, any kind of infection, trauma, thyroid diseases, without history of using drugs, such as anti- hypertensive, anti hyperlipidemia, anti-inflammatory, anti diabetic agents, drugs for weight reduction, OCP, corticosteroids, not pregnancy and lactation, not smoking. Exclusion criteria: pregnancy, breast feeding, presence of any disease and use of drugs that mentioned above, don't follow the diets

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Ghods Ave.

City

Tehran

Postal code

1417613151

Approval date

empty

Ethics committee reference number

10265

Health conditions studied

1

Description of health condition studied

Serum omentin concentration in overweight women

ICD-10 code

-

ICD-10 code description

-

2

Description of health condition studied

Overweight

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Serum omentin concentration

Timepoint

At the beginning and at the end of phase one and two

Method of measurement

Elisa kit

Secondary outcomes

1

Description

Plasma adiponectin concentration

Timepoint

At the beginning and at the end of phase one and two

Method of measurement

Elisa kit

2

Description

C- reactiv protein

Timepoint

At the beginning and at the end of phase one and two

Method of measurement

Elisa kit

3

Description

Insulin

Timepoint

At the beginning and at the end of phase one and two

Method of measurement

Elisa kit

4

Description

Fasting blood glucose

Timepoint

At the beginning and at the end of phase one and two

Method of measurement

Elisa kit

5

Description

Lipid profile(cholesterol-triglycerid-HDL-LDL)

Timepoint

At the beginning and at the end of phase one and two

Method of measurement

Elisa kit

6

Description

Weight

Timepoint

At the beginning and at the end of phase one and two

Method of measurement

Seca digital scale

7

Description

Body mass index

Timepoint

At the beginning and at the end of phase one and two

Method of measurement

Calculate

8

Description

Body fat mass

Timepoint

At the beginning and at the end of phase one and two

Method of measurement

Bioimpedance device

9

Description

Waist and hip circumference

Timepoint

At the beginning and at the end of phase one and two

Method of measurement

Meter

10

Description

Waist to hip ratio

Timepoint

At the beginning and at the end of phase one and two

Method of measurement

Calculate

11

Description

Blood pressure

Timepoint

At the beginning and at the end of phase one and two

Method of measurement

Manometer

Intervention groups

1

Description

Diet rich in olive oil with composition:51% carbohydrate.15% protein. 34% fat.8% SFA.10% PUFA.16% MUFA for six weeks

Category

Treatment - Drugs

2

Description

Common diet with composition:51% carbohydrate.15% protein. 34% fat.16% SFA.10% PUFA.8% MUFA for six weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammad Rasoulallah Hospital of Mobarakeh

Full name of responsible person

Akram Kabiri

Street address

Mohammad Rasolallah Hospital mobarakeh, Safaeeh, Mobarakeh, Esfahan

City

Mobarakeh

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Javad Hosseinzadeh

Street address

Faculty of Public health,Tehran University of Medical Sciences, Enghelab square

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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***Phone**

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Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Faculty of Public health, Tehran University of Medical Sciences

Full name of responsible person

Fahimeh Haghighatdoost

Position

Master of Nutritional Science

Other areas of specialty/work**Street address**

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Full name of responsible person

Dr. Mohammad Javad Hosseinzadeh

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Assistant professor

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Postal code**Person responsible for updating data****Contact****Name of organization / entity**

Nutrition and biochemistry group, faculty of Public health, Tehran University of Medical Sciences

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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*