

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Effects of grape seed extract supplement on anthropometric measurements, serum lipids, inflammatory markers and neuropeptide Y in overweight or obese individuals

Protocol summary

Summary

Method of this study has designed based on Double blind Randomized Clinical Trial principles. The goal of this study is the Effects of combined administration of weight reducing diet and Grape seed extract supplementation on anthropometric measurements, serum lipids, inflammatory markers and neuropeptide Y, in overweight or obese individuals ($BMI \geq 25 \text{ kg/m}^2$) with no exclusion criteria. After completing informed consent form, obese patients will be requested to be fast for 12 to 14 hours in subsequent presence. Then we will catch 5 cc venous blood from patients and they will be weighed with 100 grams precision and light clothing and will be calculated their stature without shoes with 0.5 cm precision and waist circumference and bioelectrical impedance analysis and their general characteristic will be record in data collecting sheet. Then cases will be divided to two groups. One group (case group) will be received combined administration of weight reducing diet and Grape seed extract capsules and the other group (control group) will be received weight reducing diet and placebo. Obese patients in case group will receive three capsules with 100 mg Grape seed extract daily during 12 weeks, while obese patients in control group will be receive placebo capsules. At the end of 6 week of study, in all patients anthropometric indices, weight, waist circumference and body fat composition will be again calculated. At the end of the 12 week, 5 cc blood after 12 to 14 hours fasting will be again catch from patients and anthropometric indices (weight, waist circumference and body fat composition) will be again recorded. Finally blood samples will be santrifuge for 15 minutes at 2000 rpm to separating serum component. Then serum lipids, neuropeptide Y, TNF-alpha and hs-CRP will be measured with enzymatic method. In this study sample size according to standard deviation (SD) of previous studies and equality of variance in two groups based on formula

for each group has calculated 22 patients that because of probable infusion, 25 patients in each group has considered.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015073015968N3**

Registration date: **2016-07-23, 1395/05/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-23, 1395/05/02

Registrant information

Name

Atoosa Saidpour

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
School of nutrition

Country

Iran (Islamic Republic of)

Phone

-

Email address

a.saidpour@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

National Nutrition and Food Technology Research
Institute/Drug Applied Research Center, Tabriz

Expected recruitment start date

2015-08-01, 1394/05/10

Expected recruitment end date

2015-11-01, 1394/08/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
Effects of grape seed extract supplement on anthropometric measurements, serum lipids, inflammatory markers and neuropeptide Y in overweight or obese individuals
Public title
Effects of grape seed extract supplement on anthropometric measurements, serum lipids, inflammatory markers and neuropeptide Y in overweight or obese individuals
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion: Aged 20-50 years; Body mass index above 25 kg/m² Exclusion criteria include: pregnancy, lactation; Menopause in women; History of liver disease; Kidney disease; Thyroid; Celiac; Diarrhea and Acute infection; Recent surgery; Weight loss diet in 6 months ago; Use of any drugs or supplements related to weight loss; Changes in body weight over three kilograms in 2 months ago; The use of Antioxidants supplementation in 3 months ago and Use of anticoagulants such as Aspirin, Warfarin.
Age
From **20 years** old to **50 years** old
Gender
Both
Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Beheshti University of Medical Sciences

Street address

7 Tag, Shahid Hafezi Street, Farahzadi Boulevard, Shahrak Gharb, Tehran

City

Tehran

Postal code

Approval date

2015-04-21, 1394/02/01

Ethics committee reference number

IR.SBMU.nnftri.Rec.1394.43

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E65, E66

ICD-10 code description

localized adiposity, Obesity

Primary outcomes

1

Description

Body mass Index

Timepoint

Before intervention, Six weeks after intervention, Twelve weeks after intervention

Method of measurement

calculating

2

Description

Weight

Timepoint

Before intervention, six weeks after intervention, Twelve weeks after intervention

Method of measurement

Seca scale

3

Description

Waist circumference

Timepoint

Before intervention, six weeks after intervention, Twelve weeks after intervention

Method of measurement

Meter

4

Description

Hip circumference

Timepoint

Before intervention, six weeks after intervention, Twelve weeks after intervention

Method of measurement

Meter

5

Description

Waist circumference to hip ratio

Timepoint

Before intervention, six weeks after intervention, Twelve weeks after intervention

Method of measurement

Calculating

6

Description

Body fat percentage

Timepoint

Before intervention, six weeks after intervention, Twelve weeks after intervention

Method of measurement

Bioelectrical Impedance Analysis

Secondary outcomes

1

Description

Hs-CRP concentration

Timepoint

Before intervent, twelve weeks after intervention

Method of measurement

Enzymatic method by kit

2

Description

Serum TNF-alpha concentration

Timepoint

Before intervent, twelve weeks after intervention

Method of measurement

Enzymatic method by kit

3

Description

Serum lipids concentration

Timepoint

Before intervent, twelve weeks after intervention

Method of measurement

Enzymatic method by kit

4

Description

NPY concentration

Timepoint

Before intervent, twelve weeks after intervention

Method of measurement

Enzymatic method by kit

Intervention groups

1

Description

Overweight and Obese individuals in the intervention group received 3 capsules of 100 mg of Grape seed extract for 12 weeks.

Category

Treatment - Drugs

2

Description

Patients in the control group received a placebo capsules similar to the Grape seed extract capsule for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinical Nutrition and Diet Therapy Clinic of Shahid Beheshti university of medical sciences

Full name of responsible person

Maryam Parandoosh

Street address

Baran Street, Shahrak Gharb, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti university of medical sciences

Full name of responsible person

Dr.Fatemeh Mohammadi Nasrabadi

Street address

7 Tag, Shahid Hafezi Street, Farahzadi Boulevard, Shahrak Gharb

City

Tehran

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, Shahid Beheshti university of medical sciences

Proportion provided by this source

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

2**Sponsor****Name of organization / entity**

Drug Applied Research Center, Tabriz

Full name of responsible person

Dr.Hossein Babaei

Street address

Vice chancellor for research of Tabriz University of Medical Sciences,university street, Tabriz

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Drug Applied Research Center, Tabriz

Proportion provided by this source**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**

National Nutrition and Food Technology Research Institute

Full name of responsible person

Maryam Parandoosh

Position

MS Student of Nutrition

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

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

Shahid Beheshti university of medical sciences-school of nutritio

Full name of responsible person

Dr. Atoosa Saidpour

Position

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National Nutrition and Food Technology Research Institute

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maryam.parandoosh@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