

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 addressVice 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**7 Tag, Shahid Hafezi Street, Farahzadi Boulevard,
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+98 21 2235 7483

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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

PHD of nutrition

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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