

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of oral grape seed oil consumption on inflammatory factors and insulin resistance in over weight and obese women

Protocol summary

Summary

This randomized clinical trial is designed with aim to determine the effect of grape seed oil on inflammatory factors and insulin resistance in over weight and obese women. In this study, 44 women with body mass of 27 or greater without any recent surgery are divided in two intervention and placebo group with 22 subjects. Women in two intervention and placebo groups will eat daily 15% from purified grape seed oil and sun flower oil respectively for two months. For all of the Participants, personality questionnaire and 24 hours food recall will be filled for assessment of nutrient intake and food frequency questionnaire for food habit evaluation. All of them will be given weight loss diet with 500 Kcal reduction from their daily-needed amount of calorie. The anthropometrical measurements every two weeks and biochemical measurements at first and end of the study will be repeated. Therefore the effect of purified grape seed oil will be compared with sunflower oil.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110123320N2**

Registration date: **2011-12-10, 1390/09/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-10, 1390/09/19

Registrant information

Name

Mehrangiz Ebrahimi mamagani

Name of organization / entity

Health & Nutrition faculty of Tabriz university of

medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Nutritional Research Center, Health and Nutrition Faculty, Tabriz University of Medical Sciences

Expected recruitment start date

2011-11-06, 1390/08/15

Expected recruitment end date

2012-02-04, 1390/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral grape seed oil consumption on inflammatory factors and insulin resistance in over weight and obese women

Public title

The effect of oral grape seed oil consumption on overweight and obese women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1- BMI equal or greater than 27; 2- following no weight loss or any special diet; 3-women with 20 until 50 years old. Exclusion criteria: 1- vitamin-mineral supplement consumption; 2- anti-inflammatory drugs consumption; 3- pregnancy or lactation; 4- being type 1 or 2 diabetes; 5-smoking; 6-recent illnesses; 7-

recent surgery; 8- injuries.

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

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
The Research Ethics Committee of Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences, Attar Neyshabori Street

City
Tabriz

Postal code

Approval date
2011-10-17, 1390/07/25

Ethics committee reference number
9042

Health conditions studied

1

Description of health condition studied
over weight and obesity

ICD-10 code
E66.0

ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
Inflammatory factors

Timepoint
Beginning and end of the intervention

Method of measurement
TNF- α and hs-CRP measurement with special kits

2

Description
insulin level

Timepoint
Beginning and end of the intervention

Method of measurement
measurement with special kits

3

Description
Fasting blood glucose level

Timepoint
Beginning and end of the intervention

Method of measurement
enzymatic method

Secondary outcomes

1

Description
anthropometry

Timepoint
beginning, second, fourth, sixth and end of the intervention

Method of measurement
Waist circumference, Hip circumference and weight measurement

2

Description
Energy and nutrient intake

Timepoint
beginning, second, fourth, sixth week and end of the intervention

Method of measurement
nutrient intake questionnaire

Intervention groups

1

Description
Grape seed oil consumption up to 15% of daily calorie instead of sunflower oil for two months in intervention group

Category
Prevention

2

Description

Continue to consumption of sunflower oil up to 15% of daily calorie for two months in placebo group

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheykholrais clinic

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nutritional Research Center, Health and nutrition faculty, Tabriz University of Medical Sciences

Full name of responsible person

Dr.Ostadrahimi

Street address

Block B, Third Floor, Health And Nutrition Faculty, Tabriz University Of Medical Sciences , Attar Neyshabori Street Tabriz, East Azerbaijan,Iran, Islamic Republic Of

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Nutritional Research Center, Health and nutrition faculty, Tabriz 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

Nutritional Research Center, Health and nutrition

faculty, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mehrangiz Ebrahimimamagani

Position

Nutrition, PhD

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Pardis Irandoost

Position

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Other areas of specialty/work

Street address

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Email

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