

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effects of Nigella Sativa Oil Supplementation with Weight Loss Diet on Some Anthropometric Indices, Lipid Profile and Some Inflammatory Factors in Obese Women with Various Polymorphisms of Adiponectin gene and Type 2 Isoform Peroxisome proliferator-activated receptor gamma

Protocol summary

Summary

(1)Objectives: Effects of Nigella Sativa oil supplementation with weight loss diet on some anthropometric indices, lipid profile and some inflammatory factors in obese women with various polymorphisms of adiponectin and PPAR γ 2 genes. (2)Design: Double blind randomized clinical trial. (3)Setting and conduct: 82 eligible women with body mass index 30-34.9 kg/m² randomly(with random number table) will be divided into two intervention(Nigella Sativa oil) and placebo(sunflower oil) groups. (4)Participants including major eligibility criteria: women with 25-50 years old; Body Mass Index between 30 to 34.9 kg/m²; following no weight loss diet or any special diet during 6 months ago. (5)Intervention: Intervention group: 3gr/day Nigella Sativa oil as 3 capsules of 1000 mg and control group: 3gr/day sunflower oil as 3 capsule of 1000 mg for two months. Also all participants will receive weight loss diet with 500 Kcal less than their daily-needed amount of calorie. (6) Main outcome measures: Anthropometric measurements (weight,height, waist circumference and hip circumference); Lipid profile including: Cholesterol (TC), Triglycerides(TG), Low-density lipoprotein (LDL-c), High-density lipoprotein (HDL-c); Inflammatory factors including Interleukin-6(IL-6), Tumor necrosis factor-alpha (TNF-alpha) and hs-CRP; Dietary intake (24-Hours food recall for two worked days and 1 holiday); distribution and frequency of adiponectin and Peroxisome proliferator-activated receptor gamma-2 isoform.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106191197N10**

Registration date: **2013-12-17, 1392/09/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-12-17, 1392/09/26

Registrant information

Name

Reza Mahdavi

Name of organization / entity

Faculty of Health & Nutrition, Tabriz Univ. of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Tabriz University of Medical Sciences and Nutrition Research Center of Tabriz University of Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Effects of Nigella Sativa Oil Supplementation with Weight Loss Diet on Some Anthropometric Indices, Lipid Profile and Some Inflammatory Factors in Obese Women with Various Polymorphisms of Adiponectin gene and Type 2 Isoform Peroxisome proliferator-activated receptor gamma

Public title
Effects of Nigella Sativa in Obese Women

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: women with 25-50 years old; Body Mass Index between 30 to 34.9 kg/m²; following no weight loss diet or any special diet during 6 months ago.
Exclusion criteria: taking vitamin-mineral supplement during 3 months ago; taking anti-inflammatory medications, losing weight drugs, aspirin and other anticoagulant medications; cardiovascular diseases, liver, kidney and thyroid disorders, type 1 or 2 diabetes; pregnancy and lactation; smoking

Age
From **25 years** old to **50 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **82**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization is performed by permuted block randomization (block size: 2) using RAS software.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Science

Street address
Tabriz University of Medical Science, Attar Neyshaboori Street

City
Tabriz

Postal code

Approval date
2013-11-18, 1392/08/27

Ethics committee reference number
92126

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code
E66.0

ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
Anthropometric indices

Timepoint
Beginning and at the end of the intervention(after 2 months)

Method of measurement
Height, weight, waist circumference, hip circumference measurement

2

Description
Inflammatory factors

Timepoint
Beginning and at the end of the intervention(after 2 months)

Method of measurement
Measurement of IL-6, TNF- α and hs-CRP with special kits

3

Description
Lipid profile

Timepoint
Beginning and at the end of study(2 months)

Method of measurement
Measurement of HDL-C, LDL-C, TG, TC with special kits

Secondary outcomes

1

Description
Frequency of adiponectin and PPAR gamma-2 genotypes

Timepoint
Beginning of intervention

Method of measurement

PCR-RFLP

Intervention groups**1****Description**

Intervention group: Consumption of 3 gr/day Nigella Sativa oil provided by Daana pharmaceutical company(1 gr soft gel capsule 3 times a day) with weight loss diet for 2 months

Category

Other

2**Description**

Control group: 3 gr/day sunflower oil provided by Daana pharmaceutical company(1 gr soft gel capsule 3 times a day) with weight loss diet

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sheikhoraese clinic

Full name of responsible person

Dr. Mohammad Alizadeh

Street address

Sheikhorayis clinic, Golgasht street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Reza Rashidi

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Tabriz University Of Medical Sciences , Attar Neyshabori Street, Tabriz

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Tabriz

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 of Tabriz 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**

Nutrition Research Center

Full name of responsible person

Dr. Alireza Ostadrahimi

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Tabriz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Nutrition Research Center

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**

Tabriz University of Medical Sciences, Health and nutrition faculty

Full name of responsible person

Nazli Namazi

Position

Ph.D student of nutrition

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

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Person responsible for scientific inquiries

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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