Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Nigella Sativa supplement on the expression of genes involved in insulin resistance and inflammation among obese women

Protocol summary

Study aim
Effect of Nigella Sativa supplement on the expression of genes involved in insulin resistance among obese women

Design
randomized double blind controlled clinical trial, cross-over

Settings and conduct
Of the obese women referring to the Imam Ali Clinic in Yazd, 40 people will be selected and randomly divided into two groups. The participants and investigator will not be aware of the drugs and placebo. The amount of genes expression in PBMC will be measured before and after the end of each stage of the intervention. Intervention is crossover and is performed in two stages of 8 weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Obese women with BMI between 27 to 35 kg/m2 and age between 25 to 55. Subjects should not use any drug. Should not have diabetes or pre-diabetes or dyslipidemia. Exclusion criteria: People who smoke or drink alcohol, pregnant and nursing women, People with chronic kidney or liver disease.

Intervention groups
Intervention group: capsule containing 1000 mg Nigella Sativa oil twice daily Control group: Placebo capsule containing paraffin oil twice daily

Main outcome variables
Expression of genes involved in insulin resistance in peripheral blood mononuclear cells; Fasting blood glucose; Serum insulin level; Serum leptin level; Serum IL-6 level;

General information

Reason for update
Measuring other factors related to Insulin Resistance in women with obesity and Overweight (funding provided)

Acronym

IRCT registration information
IRCT registration number: **IRCT20180430039475N1**
Registration date: **2018-06-25, 1397/04/04**
Registration timing: **prospective**

Last update: **2022-04-05, 1401/01/16**
Update count: **5**

Registration date
2018-06-25, 1397/04/04

Registrant information

Name
Sara Safi Esfahani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3230 5375

Email address
drsafi@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01

Expected recruitment end date
2019-03-20, 1397/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Nigella Sativa supplement on the expression of genes involved in insulin resistance and inflammation among obese women

Public title

Effect of Nigella Sativa supplement on the expression of genes involved in insulin resistance

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Obese women with BMI between 27 to 35 kg/m2 Age between 25 to 55 Should not use any drug Should not have diabetes or pre-diabetes or dyslipidemia

Exclusion criteria:

People who smoke or drink alcohol Pregnant and nursing women People with chronic kidney, liver disease

Age

From **25 years** old to **55 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **1**

Blood samples will be taken from all individuals before and after each period of interventions.

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization: Simple Random unit: Individual Tool: Randomized Tables A balanced block method is used to allocate concealment so that the number of samples assigned to each of the groups is equal.

Blinding (investigator's opinion)

Double blinded

Blinding description

Supplements of cumin and placebo in the same capsules in terms of size, color and shape Encodes A and B on supplements and placebo

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoughi University of Medical Sciences Yazd

Street address

School of health, Sadoughi University of Medical Sciences, Shohadaye Gomnam Blvd., Alem Sq.

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2018-04-17, 1397/01/28

Ethics committee reference number

IR.SSU.SPH.REC.1397.006

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Expression of genes involved in insulin resistance in peripheral blood mononuclear cells

Timepoint

at the beginning and end of each 2-month intervention period

Method of measurement

Reverse transcription polymerase chain reaction (RT-PCR)

2

Description

fasting blood glucose

Timepoint

at the beginning and end of each 2-month intervention period

Method of measurement

Biochemical analysis

3

Description

Serum insulin level

Timepoint

at the beginning and end of each 2-month intervention period

Method of measurement

ELISA Kit

4

Description

Serum malondialdehyde level

Timepoint
at the beginning and end of each 2-month intervention period
Method of measurement
ELISA kit

5

Description
Serum total anti-oxidant capacity
Timepoint
at the beginning and end of each 2-month intervention period
Method of measurement
ELISA kit

6

Description
serum leptin
Timepoint
at the beginning and end of each 2-month intervention period
Method of measurement
ELISA kit

7

Description
serum IL-6
Timepoint
at the beginning and end of each 2-month intervention period
Method of measurement
ELISA kit

Secondary outcomes

1

Description
Dietary intake
Timepoint
At the beginning and end of each 2-month intervention period
Method of measurement
three-day food records and 24-h food recalls questionnaires

2

Description
Expression of hormone-related genes in peripheral blood mononuclear cells
Timepoint
at the beginning and end of each 2-month intervention period
Method of measurement
Reverse transcription polymerase chain reaction (RT-PCR)

3

Description
serum level of estradiol
Timepoint
at the beginning and end of each 2-month intervention period
Method of measurement
ELISA kit

4

Description
serum level of sex-hormone binding globulin
Timepoint
at the beginning and end of each 2-month intervention period
Method of measurement
ELISA kit

Intervention groups

1

Description
Intervention group: People in this group will recieve two 1000 mg capsules of Nigella Sativa daily for 8 weeks. Then it will be wash out period for 1 month, and after that, people will receive 2 placebo capsules daily for 8 weeks.
Category
Treatment - Drugs

2

Description
Control group:people in this group will recieve two placebo capsuls daily for 8 weeks. Then it will be wash out period for 1 month, and after that, people will receive two 1000 mg capsules of Nigella Sativa daily for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali clinic
Full name of responsible person
Sara Safi Esfahani
Street address
Navab Safavi Blvd.
City
Yazd
Province
Yazd
Postal code
8915173160
Phone
+98 35 3630 1700
Email

dr.s_safi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Research Associate, School of Health
Street address
Shohadaye gomnam Blvd., Shahid Sadoughi University of Medical Sciences, School of Health
City
Yazd
Province
Yazd
Postal code
8915173160
Phone
+98 35 3820 9100
Email
sphealth@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Sara Safi Esfahani
Position
Phd Student
Latest degree
Medical doctor
Other areas of specialty/work
Nutrition
Street address
School of health, Shahid Sadoughi university of medical sciences, Shohadaye Gomnam Blvd., Alam Sq,
City
Yazd
Province
Yazd
Postal code
8915173160
Phone
+98 35 3820 9100
Email
drsafi@ssu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Azadeh Nadjarzadeh
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
School of health, Shahid Sadoughi university of medical sciences, Shohadaye Gomnam Blvd., Alam Sq,
City
Yazd
Province
Yazd
Postal code
8915173160
Phone
+98 35 3820 9100
Email
azadehnajarzadeh@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Sara Safi Esfahani
Position
PhD Student
Latest degree
Medical doctor
Other areas of specialty/work
Nutrition
Street address
School of health, Shahid Sadoughi university of medical sciences, Shohadaye Gomnam Blvd., Alam Sq,
City
Yazd
Province
Yazd
Postal code
8915173160
Phone

+98 35 3820 9100

Email

drsafi@ssu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

I have not yet decided on this.

When the data will become available and for how long

I have not yet decided on this.

To whom data/document is available

I have not yet decided on this.

Under which criteria data/document could be used

I have not yet decided on this.

From where data/document is obtainable

I have not yet decided on this.

What processes are involved for a request to access data/document

I have not yet decided on this.

Comments