

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 Gornam 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 receive 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 receive two placebo capsules 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

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Phone

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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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Azadeh Nadjarzadeh

Position

Associate professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Sara Safi Esfahani

Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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