Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Effect of oral balck cumin (Nigella Sativa) supplement on the expression of genes involved in adipogenesis and serum concentrations of liver enzymes and lipid profiles among obese and overweight women

Protocol summary

Study aim

Effect of oral black cumin (Nigella Sativa) supplement on the expression of genes involved in adipogenesis and serum concentrations of liver enzymes and lipid profiles among obese and overweight women

Design

This is a cross-over randomized placebo controlled double blind clinical trial. The target group consisted of 35 women who will randomly assigned into one of the two groups. Duration of the intervention consisted of 2 periods of 2 months;

Settings and conduct

Obese and overweight healthy women who will be referred to Imam Ali hospital in Yazd city, will be recruited and will be randomly divided into 2 groups of supplement and placebo; capsules will be given in a double-blind process; participants and researchers will be blinded to the content. Blood collection will be done to assess the biochemical factors at the beginning and the end of each period; RNA will be extracted from the blood of all participants before and after every intervention in the Internal section of hospital. RTPCR test will be performed on blood samples. After a 1-month washout, all the mentioned procedures will be done for the second period.

Participants/Inclusion and exclusion criteria

Inclusion criteria are healthy obese and overweight women aged 27 to 55 years old with the BMI ranges of 27 to 35 kg/m2; exclusion criteria includes the presence of allergy to the supplements during the intervention period or the use of less than 10% of the supplements.

Intervention groups

the treatment group will receive 2 pearls per day , that each pear contain 1000 ml of nigella sativa for 2 periods of 2 months; the placebo group will receive 2 pearls per day , that each pear contain 1000 ml of placebo for 2 periods of 2 months; one month of washout period will be performed between the 2 periods.

Main outcome variables

Adipogenesis related gene sequence; LDL-c; HDL-c; TG; TC; AST; ALT; ALK; SBP; DBP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180528039884N1**
Registration date: **2018-07-02, 1397/04/11**
Registration timing: **prospective**

Last update: **2019-02-15, 1397/11/26**
Update count: **1**

Registration date

2018-07-02, 1397/04/11

Registrant information

Name

Elham Razmpoosh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2208 3075

Email address

e.razmpoosh@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral balck cumin (Nigella Sativa) supplement on the expression of genes involved in adipogenesis and serum concentrations of liver enzymes and lipid profiles among obese and overweight women

Public title

Effects of nigella satva on obesity related gene changes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Obese women whose overweight and obesity were defined according to WHO criteria. The BMI range of participants should be between 27 to 35 kg/m2. Age ranges should be 25 to 55 years old. Healthy overweight and obese women will be interred to the study.

Exclusion criteria:

Having replacement treatments like Hormone or supplemental vitamins or weight loss drugs; tobacco and alcohol use chronic or acute inflammatory disease ; heart valve disease ; short bowel syndrome ; allergies individuals with low immune system (autoimmune diseases) pregnancy and lactation consuming less than 40% of Nigella sativa or placebo supplements. individuals who had allergy to the nigella sativa supplements.

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

Randomized

Randomization description

For the primary recruitment of participants, stratified randomization method will be used based on participants age including 25-40 and 40-55 years old. and the random number table will be used to assign participants to the intervention and control (placebo) groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The appearance and shape of the Supplements and placebos pearls will be similar; every complete packs will be given once for the first 2 months of the intervention and once before the second 2 months of the intervention. A and B labels will be fixed on the bottles of pearls by someone irrelevant to the entire study. Participants and researchers will be blinded to the contents in the bottles through out the study.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Faculty of Health, Shahid Sadoughi University of Medical Sciences

Street address

Alem Sauare

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2018-04-17, 1397/01/28

Ethics committee reference number

IR.SSU.SPH.REC.1397.007

Health conditions studied

1

Description of health condition studied

Obesity and overweight

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

Alteration in adipogenesis related gene sequence

Timepoint

Four times; at the beginning and the end of the first 2-month trial and at beginning and the end of the second 2-month trial

Method of measurement

centrifuge

2

Description

Liver enzyme, alanine aminotransferase (ALT)

Timepoint

4 times; at the initiation and the end of the first 2-month trial and at the initiation and the end of the second 2-month trial

Method of measurement

Assay Kits (Pars Azmoon Co.)

3

Description

Lipid profile

Timepoint

4 times; at the initiation and the end of the first 2-month trial and at the initiation and the end of the second 2-month trial

Method of measurement

Assay kits (Padgin Teb Co.)

4

Description

Liver enzyme, Aspartate aminotransferase

Timepoint

4 times; at the initiation and the end of the first 2-month trial and at the initiation and the end of the second 2-month trial

Method of measurement

Assay Kits (Pars Azmoon Co.)

5

Description

Liver enzyme, Alkaline phosphatase (ALK)

Timepoint

4 times; at the initiation and the end of the first 2-month trial and at the initiation and the end of the second 2-month trial

Method of measurement

Assay Kits (Pars Azmoon Co.)

Secondary outcomes

1

Description

Blood Pressure

Timepoint

4 times; at the initiation and the end of the first 2-month trial and at the initiation and the end of the second 2-month trial

Method of measurement

Mercury barometer

2

Description

anthropometric measurments

Timepoint

4 times; at the initiation and the end of the first 2-month trial and at the initiation and the end of the second 2-month trial

Method of measurement

digital anthropometric scale

Intervention groups

1

Description

Intervention group: the treatment group will receive 2 pearls of Nigella sativa per day after lunch and dinner, that each pearl contain 1000 ml of nigella sativa for 2 periods of 2 months; the pearls are produced by Barij Co.

Category

Treatment - Other

2

Description

Control group: the placebo group will receive 2 pearls per day , that each pear contain 1000 ml of placebo for 2 periods of 2 months; one month of washout period will be performed between the 2 periods. placebo will be the oral paraffin.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali clinic, related to Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Azadeh Nadjarzadeh

Street address

Alem Square

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3630 1700

Email

e_razmpoosh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Azadeh Nadjarzadeh

Street address

Alem Square

City

Yazd

Province

Yazd

Postal code

8915173160

Phone
+98 35 3820 9100

Email
azadehnajarzadeh@gmail.com

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
50

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
Azadeh Nadjarzadeh

Position
assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Alem Square

City
Yazd

Province
Yazd

Postal code
8915173160

Phone
+98 35 3820 9100

Email
azadehnajarzadeh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Azadeh Nadjarzadeh

Position
assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Alem Square

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
Azadeh Nadjarzadeh

Position
assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Alem Square- Pardis- faculty of Health

City
Yazd

Province
Yazd

Postal code
8915173160

Phone
+98 35 3820 9101

Email
azadehnajarzadeh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Some critical information such as the primary and secondary outcomes along with the informed consent form and volunteer related forms will be shared.

When the data will become available and for how

long

6 months after the publication of the first related article

To whom data/document is available

Assistant professors and researchers, giving their detailed information and the reason for achieving the information.

Under which criteria data/document could be used

the permission from the correspondence

From where data/document is obtainable

Nutrition group, Faculty of Health, Shahid Sadoughi University of Medical Sciences

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

discussing the request in Nutrition group and waiting for their assessment on the request

Comments