Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical trial comparing the effects of Nigella sativa and placebo on metabolic markers in postmenopausal women

Protocol summary

Summary

Randomized, double-blind (patients and researchers), placebo-controlled, single-center, third phase of clinical trial Main purpose is to evaluate the effect of Nigella Sativa on metabolic markers in post-menopausal women and the practical purpose is to find an effective treatment for post-menopausal women with metabolic disorders. The sample size is 70 and using randomizing blocks of two alleles, people randomly divided into two groups. Intervention in cases, including administration of Nigella Sativa at a daily dose of 500 milligrams (in addition to exercise and diet) and in control group is prescribing a placebo along with exercise and diet. Inclusion criteria consist of metabolic syndrome measures (such as abdominal obesity, high triglyceride levels, high density cholesterol level, systolic and diastolic blood pressure and fasting blood glucose level) as well as the level of total cholesterol and low density cholesterol. Moreover, these persons must have signed informed consent. Exclusion criteria include items interfere with study outcomes or prescribing drugs. Its examples include pregnancy, diabetes, gouty arthritis, blood pressure more than Stage 1, acute or chronic coronary artery disease and a history of cardiovascular events. Sample size: 70 Study time: 3 months Primary outcome variables: Fasting blood glucose, total cholesterol level, high density cholesterol level, low density cholesterol level, triglyceride level Secondary outcome variables: Blood cell count, C-reactive protein, headache, back pain, nausea, vomiting, vaginal itching, vaginal atrophy, sexual dysfunction, vaginal dryness, drowsiness, surgical history, medication, occupation, flushing, waist, weight, parity, age, skin changes, breast pain

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062122854N1**
Registration date: **2016-02-06, 1394/11/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-06, 1394/11/17

Registrant information

Name

Fatemeh Khodakarami

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparing the effects of Nigella sativa and placebo on metabolic markers in postmenopausal women

Public title
Nigella sativa effects on the menopausal complications
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: 1. Abdominal obesity: waist circumference greater than 88 cm 2. Triglyceride level of more than 150 and less than 199 milligrams per deciliter 3. High density cholesterol level less than 50 milligrams per deciliter 4. Systolic blood pressure: 139- 130 mm Hg and diastolic blood pressure: 85-89 mm Hg 5. Fasting blood glucose level of 100 to 125 milligrams per deciliter (If patients had 3 criteria or more than 3 criteria known as cases of metabolic syndrome) 6. Total cholesterol level greater than 200 and less than 239 milligrams per deciliter 7. Low density cholesterol level greater than 100 and less than 150 milligrams per deciliter 8. People who are interested in participating in the study and signed an informed consent. Exclusion criteria: 1. Pregnancy 2. Diabetes type one or two (fasting blood sugar more than 126) 3. Gouty arthritis 4. Blood pressure more than Stage 1 (systolic blood pressure over 139 mm Hg and diastolic blood pressure over 89 mm Hg) 5. Acute or chronic coronary artery disease or a history of cardiovascular events 6. Liver disorders (elevated liver enzymes more than three times normal) 7. Chronic kidney disease (creatinine level more than one and a half milligrams per deciliter) 8. A strong family history of dyslipidemia 9. Those do exercise in level of moderate or vigorous 10. Taking drugs such as supplements or drugs used in traditional medicine, the consumption of alcohol within the past month 11. Patients undergoing basic treatment of hyperlipidemia (cholesterol over 240, triglycerides 200 and Low density cholesterol levels over 150) 12. People who did not sign the consent form, tend not to follow the steps, moved to another location or have died during the study.
Age
From **45 years** old to **60 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
At the first session after history taking and based on routine tests were taken in the menopausal period, people who have the inclusion criteria enter the study. After a thorough examination, weight and waist circumference are measured and written informed consent is taken. Then their blood tests including CBC, fasting blood glucose, total cholesterol, high density cholesterol, triglycerides and CRP are checked. The kit used to measure blood sugar, triglycerides and total cholesterol belongs to Parsazmoon and measurement kit of the high density cholesterol and C-reactive protein related to Unique Company. Low density cholesterol determined through the Friedewald formula. The type of system used is RAXT type 1,000. History taking, examination, measurement of weight (using the digital scale model QC, type 6173 BV 01015, making China the power measurement Max 150 kg weight) and consent will done by a general practitioner. Blood tests perform in the laboratory of Moheb Yas Comprehensive Women's Hospital. Then people using two alleles randomization blocks of (the AABB, ABAB, ABBA, BAAB, BBAA, BABA... /control group: A, study group: B), divided into two groups. Pharmaceutical compounds packed into similar bags, so the patient or drug distributor is not aware of its contents until the opening of envelopes. At last, obtained experimental and clinical data analyze with SPSS software.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, Pursyna St., 16th Azar St., Keshavarz Blvd.
City
Tehran
Postal code
Approval date
2015-04-14, 1394/01/25
Ethics committee reference number
ir.tums.rec.1394.142954

Health conditions studied

1

Description of health condition studied
menopausal complications
ICD-10 code
N95
ICD-10 code description
Menopausal and other perimenopausal disorders

Primary outcomes

1

Description
Fasting blood sugar
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Parsazmoon lab kit, milligram per deciliter

2

Description
Total cholesterol level
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Parsazmoon lab kit, milligram per deciliter

3

Description
High density cholesterol level
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Unique lab kit, milligram per deciliter

4

Description
Low density cholesterol level
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Friedewald formula

5

Description
Triglycerid level
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Parsazmoon lab kit, milligram per deciliter

Secondary outcomes

1

Description
Nausea
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Questionnaire

2

Description
Vomiting
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Questionnaire

3

Description
Headache
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Questionnaire

4

Description
Constipation
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Questionnaire

5

Description
Drowsiness
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Questionnaire

6

Description
Vaginal dryness
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Questionnaire

7

Description
Sexual dysfunction
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Questionnaire

8

Description
Vaginal atrophy
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Examination

9

Description
Vaginal itching
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Questionnaire

10

Description
Breast pain
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Questionnaire

11

Description
Skin changes
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Questionnaire

12

Description
Age
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Questionnaire

13

Description
Parity
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Questionnaire

14

Description
Weight
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Examination

15

Description
Waist circumference
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Examination, centimeter

16

Description
Flushing
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Questionnaire

17

Description
Job
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Questionnaire

18

Description
Medicine consumption
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Questionnaire

19

Description
Surgical history
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Questionnaire

20

Description
C reactive protein
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Blood test (unique kit), milligram/liter

21

Description
Blood cell count
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Blood test, number per microliter

Intervention groups

1

Description
Intervention group 1: This group received oral placebo capsules daily, along with diet and exercise for 2 months. Placebo is made from starch and prepared by the Faculty of Pharmacy Tehran University.
Category
Placebo

2

Description
Intervention group 2: Nigella sativa extract in order to better reception, placed in vinegar for a week and then come in shape of 500 mg capsules. Tuba Salamatkadeh

produced these capsules and its brand is Shoniz. Case group received medication as daily oral capsules, along with diet and exercise for 2 months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Moheb Yas Comprehensive Women's Hospital (Mirza Kuchak Khan Hospital)

Full name of responsible person
Mahboobeh Shirazi

Street address
Moheb Yas Comprehensive Women's Hospital (Mirza Kuchak Khan Hospital)_ Shahid Nejatolahi Street_Karim Khan Zand Blvd

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person
Masud Yunesian

Street address
Department of Environmental Health Engineering, School of Public Health, Tehran University of Medical Sciences

City
Tehran

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, Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Masud Yunesian

Position
Professor

Other areas of specialty/work

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Assistant professor, Gynecologist, Perinatology fellowship

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fatemeh.khodakarami@gmail.com

Web page address

Person responsible for updating data

Contact

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