

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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

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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, Poursyna 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

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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