Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effect of Nigella sativa oil soft capsule and placebo on early menopausal symptom and serum levels of some oxidative markers in Postmenopausal women: A triple blind randomized controlled clinical trial

Protocol summary

Study aim
Effect of Nigella Sativa oil soft capsule on early menopausal symptom and serum levels of some oxidative markers in menopausal women

Design
Two parallel arm Randomized Controlled Trial

Settings and conduct
This study will be conducted at community health centers in Tabriz. A person from research team not involved in the recruitment and assigning participants will generate allocation sequence using a computerized program. Opaque sealed sequentially numbered envelops will be used for allocation concealment. Eligible women will be randomly assigned into two groups of 72 subjects with block sizes of 4 and 6, stratified by menopausal status.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 45 and 60 years; Not having a menstrual period over the past 12 months; Gaining score 15 to 42 in Green scoring system; Having a normal menopause; Menopause over the past 5 years. Non inclusion criteria: Smoking and drinking alcoholic beverages; Existence of stressors; The presence of estrogen-dependent diseases; History of liver disease; Use herbal or hormonal medications to relieve menopausal symptoms.

Intervention groups
Intervention group: Nigella Sativa oil 1000 mg soft capsule, produced by Baryj Essence pharmaceutical company, orally once a day for 8 weeks Control group: Nigella Sativa placebo soft capsule containing 1000 mg Lactose produced by Baryj Essence pharmaceutical company once a day, orally for 8 weeks.

Main outcome variables
Total and subdomains scores of early menopause symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110606006709N19**
Registration date: **2019-04-14, 1398/01/25**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-14, 1398/01/25**
Update count: **0**

Registration date
2019-04-14, 1398/01/25

Registrant information

Name
Mahnaz Shahnazi

Name of organization / entity
Tabriz University of Medical Science

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-26, 1397/10/05

Expected recruitment end date
2019-04-20, 1398/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of Nigella sativa oil soft capsule and placebo on early menopausal symptom and serum levels of some oxidative markers in Postmenopausal women: A triple blind randomized controlled clinical trial

Public title
The effect of Nigella sativa oil soft capsule on early menopausal symptom and oxidative markers

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Bing at the age of 45-60 years old Not having a menstrual period over the past 12 months Earning a score between 15-42 in the Green Assessment Hot flashes Having a normal menopause Menopause over the past 5 years (less than 5 years from start of menopause) Having a normal blood pressure (100/60 to 140 / 90)

Exclusion criteria:
The use of tobacco and alcohol The presence of stressors such as the death of relatives of the first class in the last 6 months The presence of estrogen-dependent diseases The use of certain dietary regimens And regular blackberry consumption in the individual Allergic to spices and essential substances A history of a history of liver disease, depression or hyperthyroidism The use of hormonal or herbal medicines to treat menopausal symptoms or nervous system medications for the last 3 months during the study use of hypertension druges

Age
From **45 years** old to **60 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Menopausal women aged 45- 60 years or older will be randomly assigned into two groups of recipients of training or control using random blocking method and blocks of size 4 and 6 using Random Allocation Software (RAS) with a 1: 1 assignment ratio by the person not involved in the research. To conceal the allocation, the name of group will be placed inside a consecutively numbered sealed opaque envelopes. Preparation of envelopes and sequence generation will be done by a person not involved in participant recruitment or data collection.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The drug and the placebo will be prepared by the same pharmaceutical company in identical shape, color and smell. Investigators, health care providers, outcome assessors, and statistical analyst will be blinded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی تبریز

Street address
Research department., third floor., central construction number 2., Tabriz University of Medical Sciences., Golgasht Street., Azadi Avenue

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Tabriz

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Approval date
2019-03-12, 1397/12/21

Ethics committee reference number
IR.TBZMED.REC.1397.1034

Health conditions studied

1

Description of health condition studied
menopause

ICD-10 code
N95.1

ICD-10 code description
Menopausal and female climacteric states

Primary outcomes

1

Description
Total and subdomains scores of early menopause symptoms

Timepoint
Before intervention, 4 and 8 weeks after intervention

Method of measurement
Greene scale

2

Description
Serum antioxidant levels (TAC)
Timepoint
Before interventions and 8 weeks after intervention
Method of measurement
Biochemical methods

3

Description
Serum oxidative stress index (MDA)
Timepoint
Before interventions and 8 weeks after intervention
Method of measurement
Biochemical methods

Secondary outcomes

1

Description
Frequency of hot flashes
Timepoint
Before interventions, 4 and 8 weeks after intervention
Method of measurement
Checklist for daily counts Frequency of hot flashes

Intervention groups

1

Description
Intervention group: They will use Nigella Sativa oil soft capsule 1000 mg once a day prepared by Baryj Essence pharmaceutical company, orally for 8 weeks.
Category
Treatment - Drugs

2

Description
Control group:They will use Nigella Sativa placebo soft capsule containing 1000 mg Lactose once a day, prepared by Baryj Essence pharmaceutical company, orally for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers selected in Tabriz
Full name of responsible person
Roghayeh Azami
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
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Position
Msc Student of Midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for updating data

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

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

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

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

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

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