

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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 envelopes 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1479 6770

##### Email address

mshahnazi@tbzmed.ac.ir

##### 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 drugs

**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**

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**Street address**

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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5138947977

**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

#### **Street address**

Faculty of Nursing and Midwifery, South Shariati street

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### **Web page address**

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## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Tabriz University of Medical Sciences

#### **Full name of responsible person**

Abolghasem Jouyban

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<http://researchvice.tbzmed.ac.ir>

### **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**

Roghayeh Azami

**Position**

Msc Student of Midwifery

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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## Person responsible for scientific inquiries

### Contact

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Mahnaz Shahnazi mansori

**Position**

assistant professor

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Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

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**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**

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