

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Comparative efficacy of placebo and Nigella sativa in treatment of sexual disorders in menopausal women of women general hospital

#### Protocol summary

##### Summary

In this prospective study 40 menopausal women who refer to menopausal clinic of women hospital and suffer from sexual dysfunction due to menopausal period entered into study. All participants fill questionnaire of female sexual function index, all the patients before enrolling to the groups fill informed consent. There are two arms; in group 1, 20 women take Nigella Sativa 600 mg per day for 3 months; in group 2, 20 women take placebo for 3 months. Then after 3 months again they will be evaluated with female sexual function index questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201311066246N2**  
Registration date: **2013-11-24, 1392/09/03**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-11-24, 1392/09/03

##### Registrant information

##### Name

Mojgan Asadi

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8822 0037

##### Email address

asadim@tums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Endocrinology & Metabolism Research Institute, Tehran  
University of Medical Sciences

##### Expected recruitment start date

2013-11-22, 1392/09/01

##### Expected recruitment end date

2014-09-21, 1393/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative efficacy of placebo and Nigella sativa in treatment of sexual disorders in menopausal women of women general hospital

##### Public title

The effect of Nigella Sativa on sexual dysfunction in menopausal women

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criterion: menopausal women with sexual dysfunction. Exclusion criteria: women who use HRT, antidepressants or they have history of depression, cardiovascular disorders, liver diseases, diabetes.

##### Age

From **40 years** old to **65 years** old

##### Gender

Female

##### Phase

N/A

##### Groups that have been masked

*No information*

##### Sample size

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Endocrinology & Metabolism  
Research Institute

**Street address**

Endocrinology & Metabolism Research Institute,5th  
floor,Shariati Hospital, North Karegar St.

**City**

tehran

**Postal code**

1411413137

**Approval date**

2013-04-17, 1392/01/28

**Ethics committee reference number**

00251

**Health conditions studied**

1

**Description of health condition studied**

Sexual dysfunction

**ICD-10 code**

F52

**ICD-10 code description**

Sexual dysfunction, not caused by organic disorder or  
disease

**Primary outcomes**

1

**Description**

The effect of Nigella Sativa on sexual dysfunction in  
menopausal women

**Timepoint**

3 months after use of drug

**Method of measurement**

Female Sexual Function Index questionnaire

**Secondary outcomes**

1

**Description**

The effect of Nigella Sativa on vasomotor disorders in  
menopausal women

**Timepoint**

After 3 months

**Method of measurement**

Menopause rating scale questionnaire

**Intervention groups**

1

**Description**

Intervention group: received 300mg sativa nigella oil  
once a day for three months

**Category**

Treatment - Drugs

2

**Description**

Control: received placebo orally once a day for three  
months

**Category**

Placebo

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Women General Hospital(menopause clinic)

**Full name of responsible person**

Farnaz Nayebzadeh

**Street address**

Women's General Hospital- North Nejatollahi ave-  
Poule Karim Khan Zand

**City**

Tehran

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Endocrinology & Metabolism Research Institute

**Full name of responsible person**

Neda Mehrdad

**Street address**

Endocrinology & Metabolism Research Institute,5th  
floor,Shariati Hospital, North Karegar St.

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Endocrinology & Metabolism Research Institute

**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**

Women's general hospital, TUMS

**Full name of responsible person**

Farnaz Nayeبزاده

**Position**

General physician

**Other areas of specialty/work**

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**Name of organization / entity**

Endocrinology & Metabolism Research Institute  
Tehran University of Medical Sciences

**Full name of responsible person**

Mojgan Asadi

**Position**

Assistant professor

**Other areas of specialty/work**

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**Name of organization / entity**

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Tehran University of Medical Sciences

**Full name of responsible person**

Mojgan Asadi

**Position**

Assistant professor

**Other areas of specialty/work**

**Street address**

**City**

Tehran

**Postal code**

**Phone**

**Fax**

**Email**

**Web page address**

**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*