

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Assistant professor

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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