Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Comparative study of the effects of Melissa officinalis and Foeniculum vulgare extract with Nigella sativa capsule, with placebo for reduction of hot flushing in postmenopausal women

Protocol summary

Summary

The aim of this study was to reduce flushing in women with menopause. In this double blind study, 46 postmenopausal women referring to health centers in Golestan province are examined. The criteria for inclusion in the study included consent for participation in the study, the sensitivity of the studied plants, postmenopausal women with a range The age range is 45-60. Exclusion criteria includes increased symptoms of hot flashes, the emergence of any mental illness. Randomly, one of the two groups receiving the 20 mg Citalopram tablet and black powdered capsule extract and Melissa leaf extract and fennel fruits (in the case of normal clinical trials), one gram daily after breakfast, and another group of 20 mg Citalopram tablets The placebo is consumed daily for eight weeks, divided into two months of the prescribed medications. The reduction in flushing in the post-treatment phase is compared to the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015072622490N2**
Registration date: **2017-07-09, 1396/04/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-07-09, 1396/04/18

Registrant information

Name

Shohreh Vosoogh

Name of organization / entity

Golestan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Islamic Azad University, Pharmaceutical Sciences Branch

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effects of Melissa officinalis and Foeniculum vulgare extract with Nigella sativa capsule, with placebo for reduction of hot flushing in postmenopausal women

Public title

Comparison of herbal drug with placebo in reducing hot flashes in postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Consent for participation in the study,lack of sensitivity to the studied plants, postmenopausal women with age of 45-60 exclusion

criteria: Sensitivity to the studied plants,increased symptoms of hot flushing, lack of Melissa officinalis and Foeniculum vulgare extract with Nigella sativa capsules and citalopram for more than 7 days during one month

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

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **46**

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 Islamic Azad University, Pharmaceutical Sciences Branch

Street address
No 99, Yasaman Street, Shariati Street

City
Tehran

Postal code

Approval date
2015-06-13, 1394/03/23

Ethics committee reference number
IR.IAU.PS.REC.1394.10

Health conditions studied

1

Description of health condition studied
Flushing

ICD-10 code
N95.1

ICD-10 code description
Menopausal and female climacteric states

Primary outcomes

1

Description
Reducing the amount of sweating

Timepoint
Before the study,1 month,2 month

Method of measurement
Ask the patient

Secondary outcomes

empty

Intervention groups

1

Description
Therapeutic intervention with medication (capsules containing Melissa officinalis and Foeniculum vulgare extract with Nigella sativa powder) with dose of 1 gram and citalopram 20 mg tablet for two months

Category
Treatment - Drugs

2

Description
Placebo intervention, pharmaceutical starch with dose of one gram and citalopram 20 mg tablets

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Health Centers In Golestan Province

Full name of responsible person
shohreh vosoogh

Street address

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gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research of Islamic Azad University, Pharmaceutical Sciences Branch

Full name of responsible person
Sepideh Arbabi Bid Goli

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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
Vice Chancellor for Research of Islamic Azad University, Pharmaceutical Sciences Branch
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

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Name of organization / entity
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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