

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparative efficacy of citalopram and compound of *Asperugo procumbens* and *foeniculum vulgare* in treatment of sleep disorders in menopausal women in Vali-e-Asr Hospital and women's general hospital (Mirza Koochak Khan) in 1391-1392

Protocol summary

Summary

(1) Objectives: Comparison of the efficacy of citalopram and a compound of *Asperugo procumbens* and *foeniculum vulgare* in treatment of sleep disorders, depression, sexual disorders, flushing, vaginal dryness, vaginal atrophy, vaginal itching, breast pain and skin changes in menopausal women. (2) Design: a double blind, randomized, placebo-controlled clinical trial including 60 menopausal women (3) Setting and conduct: 60 postmenopausal women with the complaint of sleep disorders, who is referred to the menopause clinic of Women's general hospital and Vali-e-Asr hospital, are studied in this trial. After taking the history and performing general and vaginal examinations, these patients are participated in the study based on the major eligibility criteria. Then they are randomly divided into 3 groups. The first group receives citalopram, the second receives the compound of *Asperugo procumbens* and *foeniculum vulgare*, and the third receives placebo. (4) Participants including major eligibility criteria: major exclusion criteria include drug consumption (eg. antidepressants, benzodiazepines), having psychological disorders such as depression, history of any medical disease such as thyroid disorders, cardiac disease, dyslipidemia, hypertension, diabetes, estrogen-dependent malignancies. Major inclusion criteria include cessation of monthly periods and confirming lab tests for menopause, having complaint of sleep disorders, negative pregnancy test, and normal lab tests including lipoprotein profile, blood sugar, thyroid and CBC in the last year. (5) Intervention: The first group will receive citalopram 40 mg (start with 20 mg and after one week increase to 40 mg) for 8 weeks, the second group will receive the compound of *Asperugo procumbens* and *foeniculum vulgare* 600mg for 8 weeks, and the third group will receive placebo for 8 weeks. (6) Main outcome

measures (variables): sleep disorders, depression, sexual disorders, flushing, vaginal dryness, vaginal atrophy, vaginal itching, breast pain, and skin changes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013072714174N1**

Registration date: **2014-01-08, 1392/10/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-08, 1392/10/18

Registrant information

Name

Mohamad Naser Jalalian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative efficacy of citalopram and compound of *Asperugo procumbens* and *foeniculum vulgare* in treatment of sleep disorders in menopausal women in Vali-e-Asr Hospital and women's general hospital (Mirza Koochak Khan) in 1391-1392

Public title

Comparison of the efficacy of citalopram and compound of *Asperugo procumbens* and *foeniculum vulgare* in treatment of menopausal disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Major exclusion criteria include drug consumption (eg. antidepressants, benzodiazepines); having psychological disorders such as depression; history of any medical disease such as thyroid disorders; cardiac disease; dyslipidemia; hypertension; diabetes; estrogen-dependent malignancies. Major inclusion criteria include cessation of monthly periods; confirming lab tests for menopause; having complaint of sleep disorders; negative pregnancy test; and normal lab tests including lipoprotein profile, blood sugar, thyroid and CBC in the last year.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 60

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 Tehran University of Medical Sciences

Street address

Central Building of Tehran University of Medical Sciences, Qods St, Keshavarz Blvd, Tehran

City

Tehran

Postal code

1417653761

Approval date

2013-07-20, 1392/04/29

Ethics committee reference number

89746

Health conditions studied**1****Description of health condition studied**

Menopausal and female climacteric states

ICD-10 code

N95.1

ICD-10 code description

Symptoms such as flushing, sleeplessness, headache, lack of concentration, associated with menopause

Primary outcomes**1****Description**

Postmenopausal sleep disorders

Timepoint

Before intervention, one month after intervention, two months after intervention

Method of measurement

Pittsburgh questionnaire

Secondary outcomes**1****Description**

depression

Timepoint

before intervention, one month after intervention, two months after intervention

Method of measurement

Standard Beck questionnaire

2**Description**

nausea

Timepoint

before intervention, one month after intervention, two months after intervention
Method of measurement
History

3

Description

flushing

Timepoint

before intervention, one month after intervention, two months after intervention

Method of measurement

History

4

Description

vomitting

Timepoint

before intervention, one month after intervention, two months after intervention

Method of measurement

History

5

Description

Headache

Timepoint

before intervention, one month after intervention, two months after intervention

Method of measurement

History

6

Description

constipation

Timepoint

before intervention, one month after intervention, two months after intervention

Method of measurement

History

7

Description

drowsiness

Timepoint

before intervention, one month after intervention, two months after intervention

Method of measurement

History

8

Description

vaginal dryness

Timepoint

before intervention, one month after intervention, two months after intervention

Method of measurement

History

9

Description

sexual disorders

Timepoint

before intervention, one month after intervention, two months after intervention

Method of measurement

History

10

Description

Vaginal atrophy

Timepoint

before intervention, one month after intervention, two months after intervention

Method of measurement

Physical Examination

11

Description

vaginal itching

Timepoint

before intervention, one month after intervention, two months after intervention

Method of measurement

History

12

Description

breast pain

Timepoint

before intervention, one month after intervention, two months after intervention

Method of measurement

History

13

Description

Skin changes

Timepoint

before intervention, one month after intervention, two months after intervention

Method of measurement

History

Intervention groups

1

Description

Citalopram Tablet 40 mg oral (start with 20mg and increase to 40mg after one week), daily for 8 weeks

Category

Treatment - Drugs

2

Description

Compound of Asperugo Procumbens and Foeniculum Vulgare, Tablet 600mg, oral, daily for 8 weeks

Category

Treatment - Drugs

3

Description

Placebo, Tablet, oral, daily for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-e-Asr Hospital

Full name of responsible person

Mahboubeh Shirazi

Street address

Emam Khomeini Hospital Complex, Bagher khan St, Tohis Sq, Tehran

City

Tehran

2

Recruitment center

Name of recruitment center

Women's general hospital (Mirza Koochak Khan)

Full name of responsible person

Mahboubeh Shirazi

Street address

Women's general hospital, North Ostad Nejatollahi St, Karim Khan Zand St, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr Shaahin Akhundzadeh

Street address

Medical School of Tehran University of Medical Sciences, Poursina St, Keshavarz Blvd, Tehran

City

Tehran

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, Tehran University of Medical Sciences

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

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Naser Jalalian

Position

MD student

Other areas of specialty/work

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Full name of responsible person

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Gynecologist, Assistant Professor

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Full name of responsible person

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Position

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Other areas of specialty/work**Street address**

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Phone**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