# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

15 Jul 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**
Pitssburgh 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**
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## Person responsible for scientific inquiries

**Contact**
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Women’s general hospital (Mirza Koochak Khan)
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## Person responsible for updating data

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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*