Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 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

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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
Name of organization / entity
Tehran University of Medical Sciences
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Mohamad Naser Jalalian
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Person responsible for scientific inquiries

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Gynecologist, Assistant Professor
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Wemon's general Hospital (Mirza Koochak Khan), North Ostad Nejatollahi St, Karim Khan Zand St, Tehran
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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