Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study of the effects of paroxetine and gabapentin in the treatment of hot flashes in postmenopausal women

Protocol summary

Summary

Objectives: To compare the effects of Paroxetine and Gabapentin in the treatment of hot flashes in menopausal women Design: Randomized, single-blind, single-center, phase II clinical trial. Postmenopausal women with hot flushes are divided into two treatment groups: Paroxetine and Gabapentin to reduce the symptoms of hot flashes. In the group treated with Gabapentin, they will receive 600 mg capsules of Gabapentin daily for up to 8 weeks (56 days). Patients in the Paroxetine group will receive one Paroxetine capsule in the morning or before bed for 8 weeks (56 days). The amount of hot flashes is measured before and after treatment. The main inclusion criteria included: The Women who have hot flashes with sweats on average 7 times or more and have menstrual periods cessation for more than 12 months. Exclusion criteria included: Women with a history of chemotherapy; radiation therapy; depression; systemic diseases; liver disease; cancer and diseases that cause hormonal disorders. Interventions: Patients are divided into two treatment groups: paroxetine and gabapentin. In the group treated with gabapentin, they will receive 600 mg capsules of gabapentin daily for up to 8 weeks (56 days). Patients in the paroxetine group will receive one paroxetine capsule in the morning or before bed for 8 weeks (56 days). Main outcome: The amount of hot flashes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201704143461N8**
Registration date: **2017-10-22, 1396/07/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-10-22, 1396/07/30

Registrant information

Name

Firoozeh Veisi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 83 1823 4276

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-05-10, 1396/02/20

Expected recruitment end date

2017-06-09, 1396/03/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effects of paroxetine and gabapentin in the treatment of hot flashes in postmenopausal women

Public title

Effects of paroxetine and gabapentin on hot flashes in postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: The Women who have hot flashes with sweats on average 7 times or more and have more than 12 months of menstrual cessation. Exclusion criteria: Women with a history of chemotherapy; radiation therapy; depression; systemic diseases; liver disease; cancer and diseases that cause hormonal disorders.
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Vice Chancellor for research، Building No. 2, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.
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Postal code
Approval date
2015-05-04, 1394/02/14
Ethics committee reference number
IR.kums.rec.1395.9310109009

Health conditions studied

1

Description of health condition studied
Flushing
ICD-10 code
R23.2
ICD-10 code description
Flushing

Primary outcomes

1

Description
Flushing
Timepoint
Before and after treatment
Method of measurement
Based on MRS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Group A: Each day, up to 8 weeks (a 56-day course), received 600 mg capsule of gabapentin.
Category
Treatment - Drugs

2

Description
Group B: Each day, up to 8 weeks (a 56-day course), received 600 mg capsule of paroxetine.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza (AS) Hospital
Full name of responsible person
Firouzeh Veisi
Street address
Department of obstetrics and gynecology, Imam Reza Hospital, Sorkhalizheh
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences
Full name of responsible person
Behrouz Hamzeh

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Vice Chancellor for research، Building No. 2, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.
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Kermanshah
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, Kermanshah 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
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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