

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 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)

###### Phone

+98 83 1823 4276

###### Email address

f\_veisi@kums.ac.ir

##### 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.

##### City

Kermanshah University of Medical Sciences, Kermanshah

##### 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

**Street address**

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

**City**

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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Firozeh Vaysi

**Position**

Assistant Professor

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

Department of obstetrics and gynecology, Imam Reza  
Hospital, Sorkhalizheh.

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**Position**

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**Full name of responsible person**

Tabasom Azadian

**Position**

Resident of Obstetrics and Gynecology

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Department of obstetrics and gynecology, Imam Reza  
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**Web page address****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*