

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jul 2026

### The efficacy of Gabapentin in the management of post menopausal sleep disorder and life quality

#### Protocol summary

##### Summary

The goal of research is the study of Gabapentine efficacy in the treatment of sleep disturbance and life quality of menopausal women. The method of study is randomized ,triple blind ,placebo controlled clinical trial .Study population menopausal women referred to Thaleghani Hospital.Inclusion criteria :Passing at least 1 year after last menstrual period ,absence of any physical or psychiatric disease ,dont using any drug and alcohol and smoking ,a score of at least 5 in Pittsburg sleep quality index ,informed written consent . Exclusion criteria :Occuring of any physical or psychiatric disease during study which causes sleep disturbance ,noncompliance . 270 patients are randomly divided in 2 groups (intervention and control).Intervention group receive gabapantin 300 mg twice daily for 12 weeks and controlled group receive placebo for 12 weeks. Primary outcome is change in the scores of Pittsburg sleep quality index and SF36 quality of life questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201304184686N3**

Registration date: **2013-04-29, 1392/02/09**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-04-29, 1392/02/09

##### Registrant information

##### Name

Mehri Jamilian

##### Name of organization / entity

School of Medicine, Arak University of Medical

Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 1278 0660

##### Email address

mjamilian@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice president of education and research, Arak University of Medical sciences

##### Expected recruitment start date

2013-05-01, 1392/02/11

##### Expected recruitment end date

2013-09-01, 1392/06/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The efficacy of Gabapentin in the management of post menopausal sleep disorder and life quality

##### Public title

The efficacy of Gabapentin in the management of post menopausal sleep disorder and life quality

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: passing at least 1 year after last menstrual period; absence of any physical or psychiatric disease; do not using any drug and alcohol and smoking; a score of at least 5 in Pittsburg sleep quality index; informed written consent. Exclusion criteria: occurring of any physical or psychiatric disease during study which causes sleep disturbance and

noncompliance.

**Age**  
No age limit

**Gender**  
Female

**Phase**  
2

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **270**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**  
Arak University of Medical Sciences

**Street address**  
basij square

**City**  
Arak

**Postal code**  
3819691187

**Approval date**  
2013-04-08, 1392/01/19

**Ethics committee reference number**  
6-143-92

## Health conditions studied

### 1

**Description of health condition studied**  
Sleep disturbance

**ICD-10 code**  
F51

**ICD-10 code description**  
Nonorganic sleep disorders

## Primary outcomes

### 1

**Description**

Pittsburg sleep quality index

**Timepoint**  
before intervention and at the end of intervention

**Method of measurement**  
clinical examination

### 2

**Description**  
quality of life questionnaire SF36

**Timepoint**  
before intervention and the end of intervention

**Method of measurement**  
clinical examination

## Secondary outcomes

### 1

**Description**  
Somnolance and dizzines

**Timepoint**  
Before intervention and at the end of intervention

**Method of measurement**  
Clinical examination

## Intervention groups

### 1

**Description**  
Interventionl group recieve Gabapentin300 mg twice daily for 12 weeks

**Category**  
Treatment - Drugs

### 2

**Description**  
Control group recieve placebo twice daily for 12 weeks.

**Category**  
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**  
Taleghani Hospital

**Full name of responsible person**  
Mehri Jamilian

**Street address**  
Taleghani Hospital

**City**  
Arak

## Sponsors / Funding sources

# 1

## Sponsor

### Name of organization / entity

Arak University Medical of Sciences

### Full name of responsible person

Dr.Ashtiany

### Street address

Basij square

### City

Arak

## Grant name

## Grant code / Reference number

## Is the source of funding the same sponsor organization/entity?

Yes

## Title of funding source

Arak University Medical of 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

Arak University of Medical Sciences

#### Full name of responsible person

Mehri jamilian

#### Position

Board of Obstetric and Gynecology,Assistant professor

#### Other areas of specialty/work

#### Street address

Taleghani Hospital

#### City

Arak

#### Postal code

#### Phone

+98 86 1278 0660

#### Fax

#### Email

MJAMILIAN@arakmu.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

### Name of organization / entity

Arak Unicesvterity of Medical Sciences

### Full name of responsible person

Mehri Jamilian

### Position

Board of Obstetric

### Other areas of specialty/work

### Street address

Basij square

### City

Arak

### Postal code

### Phone

+98 86 1278 0660

### Fax

### Email

mjamilian@arakmu.ac.ir

### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Arak University of Medical Sciences

#### Full name of responsible person

Mehri Jamilian

#### Position

Assistant professor .Board of Obstetric

#### Other areas of specialty/work

#### Street address

Taleghani Hospital

#### City

Arak

#### Postal code

#### Phone

+98 86 1278 0660

#### Fax

#### Email

mjamilian@yahoo.com

#### 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