Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 distorbance and life quality of menopausal women. The method of study is randomized ,triple blind ,placebo controlled clinical trial .Study population menopausal women reffered to Thaleghani Hospital.Inclusion criteria :Passing at least 1 year after last menstural period ,absence of any physical or psychiatric disease ,dont using any drug and alcohale 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 recieve gabapantin 300 mg twice daily for 12 weeks and controlled group recieve placebo for 12 weeks. Primary outcome ic 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 menstural period; absence of any physical or psychiatric disease; do not using any drug and alcohale 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 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 Unicesversity 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