Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Randomized placebo controlled clinical trial of the efficacy of Gabapentin on flushing in menopausal women

Protocol summary

Summary

This randomized single blind placebo controlled clinical trial will be conducted on sixty menopausal women, who elapse from their last menstruation at least one year and FSH level more than 40 IU/L. Exclusion criteria are: consumption of any drugs for flushing , having systemic diseases, happening the Gabapentin complications noncompliance .The aim of this study is to evaluate the efficacy of Gabapentin on the severity of flushing. The patients will randomly assign into intervention and control groups. In intervention group patients will take Gabapentin capsules (300mg), three times a day, for three months. The control group will receive placebo capsules (consist of starch) three times a day for three months. Primary outcome measure is the severity of flushing measured by visual analog scale at the beginning , first, second and third months after drug consumption. The results will be compared in study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103011107N4**
Registration date: **2011-05-05, 1390/02/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-05-05, 1390/02/15

Registrant information

Name
Tajea Jadery

Name of organization / entity
Jundi shapur university

Country
Iran (Islamic Republic of)

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-

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Recruitment status
Recruitment complete

Funding source
Jundshapour University of Medical Sciences

Expected recruitment start date
2010-06-22, 1389/04/01

Expected recruitment end date
2010-10-23, 1389/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Randomized placebo controlled clinical trial of the efficacy of Gabapentin on flushing in menopausal women

Public title
Efficacy of Gabapentin on flushing in menopausal women

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria : Elapsing one year of last menstrual phase(LMP), Follicle-stimulating hormone (FSH) more than 40IU/L and not using any drugs that affect on hot flush symptoms. Exclusion criteria : happening Gabapentin side effects, noncompliance and coexistence of systemic disease

Age
From **40 years** old to **55 years** old

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)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ahwaz Jondishapur University of Medical Sciences
Street address
Ahwaz
City
Golestan Bolvar,Ahvaz
Postal code
Approval date
2010-06-07, 1389/03/17
Ethics committee reference number
2380

Health conditions studied

1

Description of health condition studied
Flushing
ICD-10 code
N95.1
ICD-10 code description
Menopausal and female climacteric states

Primary outcomes

1

Description
Flushing severity
Timepoint
Before intervention, 1 month after intervention, 2months later and 3 months later after intervention
Method of measurement
Visual Analoge Scale

Secondary outcomes

1

Description
Flushing duration
Timepoint
Before intervention, 1 month after intervention, 2months later and 3 months later after intervention
Method of measurement
Patients notation

Intervention groups

1

Description
Intervention group: Gabapentin Capsule 300 mg- TDS- during 3 months
Category
Treatment - Drugs

2

Description
Control group: Placebo as capsules, three times a day for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Khomeini Hospital
Full name of responsible person
Solmaz Natanj
Street address
Ahvaz Emam Khomeini Hospital
City
Ahwaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jundishapour Medical University
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Vice-Chancellor For Research, Ahvaz Jundishapour University of Medical Science
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Jundishapour Medical University
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
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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