Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the efficacy of prophylaxis with Pregabalin and Sodium Valproate on intensity and frequency of migraine type headache in Iranian patients

Protocol summary

Summary

The purpose of this study is to compare the efficacy of prophylaxis with Pregabalin and Sodium Valproate in adult patients with diagnosis of migraine type headache based on International Headache Society criteria. In this prospective, randomized, double blind, 2-armed parallel group clinical trial, 100 patients with diagnosis of migraine and will be recruited from neurology clinic, Imam Hussein hospital, Tehran, Iran. All subjects with history of prophylactic treatment for migraine will be excluded. After randomization of the subject, 50 subjects in group A will receive Pregabalin 75mg twice daily and 50 subjects in group B will receive Sodium Valproate 200mg twice daily for 3 months. Primary outcome measures are comparison of frequency and intensity of migraine headaches in patients receiving Sodium Valproate as standard prophylactic regimen with Pregabalin (time frame: baseline, 1, 2 and 3 months after intervention). Intensity of headache will be evaluated by Wong-Baker Faces Pain Rating Scale

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012070310178N1**
Registration date: **2013-04-21, 1392/02/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-04-21, 1392/02/01

Registrant information

Name

Mohammad Sistanizad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2014-01-20, 1392/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of prophylaxis with Pregabalin and Sodium Valproate on intensity and frequency of migraine type headache in Iranian patients

Public title

Comparison of Pregabalin and Sodium Valproate on prophylaxis of migraine type headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:all patients with diagnosis of migraine based on International Headache Society criteria.
Exclusion criteria: other types of headache; administration of prophylactic treatment for migraine; pregnancy; breast feeding; sensitivity to Pregabalin or

Sodium Valproate.

Age
From **15 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Imam Hussein hospital

Street address
Shahid Madani Street

City
Tehran

Postal code

Approval date
2012-07-02, 1391/04/12

Ethics committee reference number
134-9663

Health conditions studied

1

Description of health condition studied
Migraine

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
frequency of migraine type headaches

Timepoint
entrance to study, 1, 2 and 3 months after intervention

Method of measurement
history taking and patient's notes

2

Description
intensity of migraine headaches

Timepoint
entrance to study, 1, 2 and 3 months after intervention

Method of measurement
Wong-Baker Faces Pain Rating Scale

Secondary outcomes

1

Description
consumption of analgesics

Timepoint
entrance to the study, 1, 2 and 3 months after intervention

Method of measurement
history taking and patient's notes

Intervention groups

1

Description
Control: Sodium Valproate 200 mg BID for 3 months

Category
Treatment - Drugs

2

Description
Intervention: Pregabalin 75mg twice daily for 3 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Neurology clinic, Imam Hussein hospital

Full name of responsible person
Omid Hesami

Street address
Shahid Madani Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Tahereh Shams
Street address
Velenjak Street, Shahid Chamran High Way
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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

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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