

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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)

Phone

+98 21 8820 0087

Email address

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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

City

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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**Contact****Name of organization / entity**

Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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