Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of efficacy of Levetiracetam with Sodium Valproate in the treatment of Chronic Migraine Headache in patients referred to Ahvaz Golestan Hospital

Protocol summary

Summary

In this study efficacy of Levetiracetam comparison with Sodium Valproate in the treatment of Chronic Migraine Headache and if Levetiracetam had an equivalent or better effect (statistically significant) than sodium valproate in reduction of headache severity,frequency and Midas score or fewer complications, Sodium Valproate can be replaced Levetiracetam .Patients 15 to 50 years old referred to Ahvaz Golestan Hospital Neurologic Clinic that according to the criteria of the International Headache Society (IHS) have chronic migraine headache to be put under study, if not pregnancy and history of liver or kidney disease.Initially, 10 patients were divided into two groups according to the results of the pilot study examined and the final sample size is calculated. The patients were randomized block into 2 groups.One group are given Sodium Valproate of Sanofi company whit Depakine comercial name and the other group are given Levetiracetam of Cobel company with Levebel comercial name for 3 months. At the end of the first and third month after the first dose, patients are seen and the efficacy of treatment based on the headache in frequency, intensity and changes in MIDAS scores by their patients with headache severity grading scale from 0 to 10 is recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015022812781N2**
Registration date: **2015-03-12, 1393/12/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-03-12, 1393/12/21

Registrant information

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Recruitment status

Recruitment complete

Funding source

Ahvaz University Of Medical Siences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of Levetiracetam with Sodium Valproate in the treatment of Chronic Migraine Headache in patients referred to Ahvaz Golestan Hospital

Public title

Comparison of efficacy of Levetiracetam with Sodium Valproate in the treatment of Chronic Migraine Headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with chronic migraine headache according to the International Headache Society criteria , (having headache 15 or more days per month with at least 8 days per month fulfilling International Headache Society criteria for migraine for at least 3 months) in the absence of ongoing medication overuse; Women have a negative pregnancy test and have appropriate contraception during the study period; No history of liver disease and kidney; No headaches other than migraine-like headaches included tension headache,sinus headache disorder,structural or post traumatic headache and Exclusion criteria: The incidence of side effects such as gastrointestinal or any other unwanted side effects caused by drug; Do not use the medication in groups for three consecutive days or a week of intermittent.

Age

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

Gender

Both

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)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz University of Medical Siences

Street address

Department of Development Studies, Ahvaz University of Medical Siences, Golestan Blvd.

City

Ahvaz

Postal code

Approval date

2014-06-16, 1393/03/26

Ethics committee reference number

ajums.rec.1393.122

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura [common migraine]

2

Description of health condition studied

Migraine

ICD-10 code

G43.1

ICD-10 code description

Migraine with aura [classical migraine]

Primary outcomes

1

Description

MIDAS Score

Timepoint

1 and 3 months after starting treatment

Method of measurement

Based on a standard questionnaire MIDAS

2

Description

Intensity of headache

Timepoint

1 and 3 months after starting treatment

Method of measurement

Pain severity grading scale by the patient with headache severity from grade 0 to 10

3

Description

Frequency of headache

Timepoint

1 and 3 months after starting treatment

Method of measurement

Headache days per month

Secondary outcomes

empty

Intervention groups

1

Description

Intervention:Levebel 500-1000 mg Oral Twice daily for 3 months

Category

Treatment - Drugs

2

Description
Control: Depakine 500-1000 mg Oral Twice daily for 3 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Golestan Hospital Neurologic Clinic
Full name of responsible person
Mehrnoush Siavashi
Street address
Golestan hospital, Farvardin Avenue, Golestan Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Siences
Full name of responsible person
Seyed Ahmad Hoseiny
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Department of Technology and Research Development, Ahvaz University of Medical Siences, Golestan Blvd.
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Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Siences
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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Email
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