Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Zonisamide versus Topiramate in migraine prophylaxis: a double-blind randomized clinical trial

Protocol summary

Summary
The aim of this study was to compare the efficacy of Zonisamide with Topiramate in decreasing the frequency and severity of migraine attacks. A total of 80 patients, recruited from referred migraineurs to our neurology clinic, who met the inclusion criteria, were randomly allocated to group A or B. In group A, the patients received Zonisamide, 50 mg daily that gradually titrated up to 200mg/d while in group B; the patients received Topiramate, 25mg daily that gradually titrated up to 100mg/d. Each patient was followed for 12 weeks and was assessed at the baseline, the fourth and twelfth weeks for the number of attacks, headache severity, need for acute medication, MIDAS score, and adverse effects.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT201011075117N1**
Registration date: **2011-01-28, 1389/11/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2011-01-28, 1389/11/08

Registrant information

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Vahid Abbasi
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source
Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date
2009-07-08, 1388/04/17
Expected recruitment end date
2010-03-08, 1388/12/17
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Zonisamide versus Topiramate in migraine prophylaxis: a double-blind randomized clinical trial

Public title
Comparation the efficacy of zonisamide and topiramate in migraine prophylaxis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: history of classic or common migraine that met International Headache Society (HIS) criteria, which is at least one year of past disease, number of migraine attacks at least four times per month and less than 15 times per month, or even when they occur less than four times per month but migraine attacks are very prolonged and debilitating that require preventive treatment, postmenopausal women who pass at least one year of their menopause, negative pregnancy test, using appropriate contraceptive during the study, no consumption of topiramate or Zonisamide Exclusion criteria: suffering from other than migraine headaches such as tension headaches, periodic headaches and

sinusitis, presence of any cause of pain that must be used medications regularly, history of hypersensitivity to topiramate or zonisamide

Age
From **12 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

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 Jundishapur University of Medical Sciences

Street address
Golestan street, ahvaz

City
Ahvaz

Postal code
-

Approval date
2009-06-14, 1388/03/24

Ethics committee reference number
1463/20/8/پ

Health conditions studied

1

Description of health condition studied
Migraine

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
Headache frequency

Timepoint
before trial , 1 month and 3 month after trial

Method of measurement
Questionnaire

2

Description
Use of acute medication

Timepoint
before trial , 1 month and 3 month after trial

Method of measurement
Questionnaire

3

Description
Headache severity

Timepoint
before trial , 1 month and 3 month after trial

Method of measurement
Questionnaire

4

Description
MIDAS score

Timepoint
before trial and 3 month after trial

Method of measurement
Questionnaire

Secondary outcomes

1

Description
Drugs complications

Timepoint
before trial, 1 month and 3 months after trial

Method of measurement
Questionnaire

Intervention groups

1

Description
Zonisamide capsule, 50-200 mg once day for 3 months in the intervention group

Category
Treatment - Drugs

2

Description
topiramate tablet 25-100 mg/day BID or twice in day for 3 month in control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology clinic in Golestan hospital
Full name of responsible person
Dr Vahid Abbasi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
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Research department of Medical School of Ahvaz Jundishapur University of Medical Sciences
Street address
Jundishapur University of Medical Sciences, Golestan street, Ahvaz
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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
Ahvaz Jundishapur 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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Person responsible for updating data

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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