Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

The effect of Topiramate in improvement of clinical status of migraineurs according to HIT6 and MIDAS questionnaires

Protocol summary

Summary

This is a clinical trial and the aim of this study was evaluation of Topiramate effect in improvement of clinical status of migraine patients. 89 patients with these criteria were enrolled: diagnosed for migraine based on the International Headache Society (IHS) criteria by a neurologist, having headache not more than 14 days per month, a history of 3 to 12 attacks. The exclusion criteria were: non-migraine headaches such as tension and sinus headaches, severe depression and a history of medical diet failure. Topiramate 25 mg/d will be prescribed for them in the first week and will be increased 25 mg/d weekly up to 100 mg/d and the maximum dose continued for 3 months, then HIT6 (Headache impact test 6) and MIDAS (Migraine Disability Assessment Scale) were refilled for patients to estimate the grade of migraine headache.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011164786N2**
Registration date: **2010-12-19, 1389/09/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-12-19, 1389/09/28

Registrant information

Name

Seyed Ali Sonbolestan

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1233 1401

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Recruitment status

Recruitment complete

Funding source

Isfahan university of medical sciences

Expected recruitment start date

2009-08-23, 1388/06/01

Expected recruitment end date

2010-08-23, 1389/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Topiramate in improvement of clinical status of migraineurs according to HIT6 and MIDAS questionnaires

Public title

The effect of Topiramate in migraine improvement

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosed for migraine based on the International Headache Society (IHS) criteria by a neurologist, having headache not more than 14 days per month, a history of 3 to 12 attacks. Exclusion criteria: non-migraine headaches such as tension and sinus headaches, severe depression and a history of medical diet failure.

Age

No age limit

Gender

Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **89**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan neuroscience research center, Isfahan university of medical sciences
Street address
Hezar jerib St.
City
Isfahan
Postal code
Approval date
2010-10-30, 1389/08/08
Ethics committee reference number
051/24/1033

Health conditions studied

1

Description of health condition studied
Migraine
ICD-10 code
G43
ICD-10 code description
Migraine

Primary outcomes

1

Description
The clinical status of patient's migraine according to HIT6 questionnaire
Timepoint
beginning and end of the study (after 3 months)
Method of measurement
history and physical exam

2

Description
The clinical status of patient's migraine according to MIDAS questionnaire
Timepoint
beginning and end of the study (after 3 months)
Method of measurement
history and physical exam

Secondary outcomes

1

Description
side effects of Topiramate in patients
Timepoint
end of the study (after 3 months)
Method of measurement
history and physical exam

Intervention groups

1

Description
Topiramate 25 mg/d will be prescribed for the patients in the first week and will be increased 25 mg/d weekly (up to 100 mg/d) and the maximum dose will be continued for 3 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellery for research, Isfahan university of medical sciences
Full name of responsible person
Dr. Peiman Adibi
Street address
Hezar jerib St.
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Vice chancellery for research, Isfahan 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
Isfahan university of medical sciences
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Seyed Ali Sonbolestan
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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