

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of efficacy of topiramate and propranolol in prophylaxis of migraine headache in children

Protocol summary

Summary

Migraine is the most important and frequent type of headache in children. Prophylactic therapy should be considered if a child experiences more than two to four severe episodes monthly or is unable to attend school regularly. The purpose of this study is to compare efficacy and safety of propranolol and topiramate in prophylaxis of migraine headache in children. In this study , eighty 5-15 year old children with migraine headache whom were referred to pediatric neurology clinic of Shahid Sadoughi University of Medical Sciences and prophylactic therapy indicated in them , are evaluated . The children are distributed into two groups. In both groups, oral drug and in two divided doses will be prescribed. In one group , 5mg/kg/day of topiramate and in other one , 1mg/kg/day of propranolol will be given . Number , severity and disability score of migraine headache and side effects of drugs are to be compared before and three months after treatment .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111282639N6**

Registration date: **2011-12-05, 1390/09/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-05, 1390/09/14

Registrant information

Name

Razieh Fallah

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd,

Iran

Country

Iran (Islamic Republic of)

Phone

+98 35 3822 4000

Email address

fallah@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Expected recruitment start date

2011-05-22, 1390/03/01

Expected recruitment end date

2011-12-22, 1390/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of topiramate and propranolol in prophylaxis of migraine headache in children

Public title

Topiramate and propranolol in migraine of children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1. children aged 5-15 years 2. Having migraine headache based on International Headache Society Criteria 3. Having also at least two episode of migraine headache in one month 4. No previous prophylactic therapy Exclusion Criteria: 1. History of drug allergy 2. Secondary headaches such as epilepsy or other neurologic disorders 3. Systemic diseases such as asthma, diabetes mellitus , metabolic acidosis , renal

stone and hepatic diseases
Age
From **5 years** old to **15 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)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Sadoughi University of Medical Sciences, Yazd,
Iran
Street address
Yazd,Alem square
City
yazd
Postal code
Approval date
2011-11-08, 1390/08/17
Ethics committee reference number
65767/1/17/پ

Health conditions studied

1

Description of health condition studied
Migraine headache
ICD-10 code
G43.0
ICD-10 code description
Migraine without aura [common migraine]

Primary outcomes

1

Description

Number of headache in a month
Timepoint
before and three months after treatment .
Method of measurement
asking from patient

2

Description
pediatric disability score of migraine headache
Timepoint
before and three months after treatment .
Method of measurement
asking from patient

3

Description
severity of headache
Timepoint
before and three months after treatment .
Method of measurement
asking from patient

Secondary outcomes

1

Description
Side effect
Timepoint
monthly until three months after treatment
Method of measurement
clinical exam

Intervention groups

1

Description
5mg/kg/day of oral topiramate for three months
Category
Prevention

2

Description
1mg/kg/day of oral propranolol for three months
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Pediatric neurology clinic of Shahid Sadoughi
University of Medical Sciences, Yazd, Iran
Full name of responsible person
Dr.Razieh Fallah
Street address

City
Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd,
Iran

Full name of responsible person

Dr.Fatemah Ezoddini

Street address

Yazd, Bahonar square

City

Yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences, Yazd,
Iran

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

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd,
Iran

Full name of responsible person

Dr.razieh Fallah

Position

Pediatric neurologist-Assisstant professor

Other areas of specialty/work

Street address

Shahid Sadoughi Hospital, Pediatric Ward

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Fax

Email

FALLAH@ssu.ac.ir

Web page address

Person responsible for updating data

Contact

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