Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)
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+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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Postal code
Phone
+98 35 1822 4000
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