

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The prophylactic effect of Topiramate and Propranolol on 3-15 years old children suffering migraine in Mofid hospital.

Protocol summary

Summary

Headache is a common disabling neurological disorder and migraine comprises more than half the causes of recurrent headaches in children. Despite extended prevalence of this type of headache there is lack of evidence about best drug treatment for migraine. So we aimed to compare the therapeutic effects of these drugs on childhood migraine. Seventy eight children (aged 3-15 years old) with migraine diagnosed according to 2004 International Headache Association criteria are enrolled in the study. These patients are matched based on gender and age and Propranolol and Topiramate will be allocated randomly to the patients. Two and six months after starting treatment, the efficacy of these 2 drugs will be measured based on frequency, severity and duration of migraine attacks and compared with the baseline parameters.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206133967N2**

Registration date: **2012-12-14, 1391/09/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-14, 1391/09/24

Registrant information

Name

Seyed Hassan Tonekaboni

Name of organization / entity

Mofid children hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 2290 9559

Email address

tonekaboni@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-06-13, 1391/03/24

Expected recruitment end date

2013-10-16, 1392/07/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The prophylactic effect of Topiramate and Propranolol on 3-15 years old children suffering migraine in Mofid hospital.

Public title

The prophylactic effect of Topiramate and Propranolol on children suffering Migraine

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria: 1-Diagnosis of headache based on international headache criteria 2-Frequencies of 3 or more per month 3-Aging 3-15 years 4-Sever disabling headache Exclusion criteria: Suffering from asthma

Age

From **3 years** old to **15 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 96

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Next to Taleghani hospital, Evin, Shahid Chamran highway, Tehran, Iran.

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

88-01-146-6379-2101

Health conditions studied

1

Description of health condition studied

migraine

ICD-10 code

G43

ICD-10 code description

Migraine with aura [classical migraine] Migraine: aura without headache basilar equivalents familial hemiplegic with: acute-onset aura prolonged aura typical aura

Primary outcomes

1

Description

Frequency of migraine attacks

Timepoint

Before, 1 month after and 6 months after treatment

Method of measurement

Observation and interview by the physician followed by filling questionnaire. This questionnaire was designed by researchers of this study.

2

Description

Severity of migraine attacks

Timepoint

Before, 1 month after and 6 months after treatment

Method of measurement

Observation and interview by the physician followed by filling questionnaire. This questionnaire was designed by researchers of this study.

3

Description

Duration of migraine attacks

Timepoint

Before, 1 month after and 6 months after treatment

Method of measurement

Observation and interview by the physician followed by filling questionnaire. This questionnaire was designed by researchers of this study.

Secondary outcomes

empty

Intervention groups

1

Description

The control group will receive Propranolol 2-4 mg/kg daily for 2 months. Propranolol is in the form of 10 mg tablets. The name of manufacturer is Hakim Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

The intervention group will receive Topiramate 50-100 mg/kg daily for 2 months. Topiramate is in the form of 20 and 50 mg tablets. The name of manufacturer is Arya Pharmaceutical Company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children's Hospital

Full name of responsible person

Dr.Ali Khajeh
Street address
Mofid Children's Hospital, Shariati Avenue, Tehran,
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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Shahid Beheshti
University of Medical Sciences
Full name of responsible person
Dr. Rahmati, Vice chancellor for research at Shahid
Beheshti University of Medical Sciences
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Shahid Beheshti University of Medical Sciences, Evin,
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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

Vice chancellor for research, Shahid Beheshti 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
Mofid Children's Hospital
Full name of responsible person
Dr.Ali Khajeh
Position
Child Neurologist
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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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