Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Public title
The prophylactic effect of Topiramat 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 Topiramat 50-100 mg/kg daily for 2 months. Topiramat 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, Iran.

City

Tehran

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

Street address

Shahid Beheshti University of Medical Sciences, Evin, Chamran highway, Tehran, Iran.

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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

Dr. Seyed Hassan Tonekaboni

Position

Pediatric Neurologist

Other areas of specialty/work

Street address

PNRC office, 2nd floor, Mofid children's hospital, Shariati Avenue, Tehran, Iran.

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mofid Children's Hospital

Full name of responsible person

Negar Hatami

Position

Doctoral degree

Other areas of specialty/work

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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