

# 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,  
Iran.  
**City**  
Tehran

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+98 21 2222 0254  
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aliyavar@yahoo.com  
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## 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.  
**City**  
Tehran

#### 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**  
**Street address**  
Mofid Children's Hospital, Shariati Avenue, Tehran,  
Iran.  
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15468-15514  
**Phone**  
+98 21 2290 9559

## 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**  
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## Person responsible for updating data

#### Contact

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Negar Hatami  
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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*