

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison the effect of Propranolol and Topiramate in Pediatric Migraine prophylaxis

Protocol summary

Summary

The object of this study is to Compare the effect of Propranolol and Topiramate in Pediatric Migraine prophylaxis. This study is a Single blind Randomized Controlled Clinical Trial on 60 Children at age of 5-15 yr in 2 equal group with Common Migraine IHS Criteria & History of Headache in last 6 months, no Drug history of Propranolol or Topiromate or other prophylactic drugs one month prior to study & with at least 2 episode of Migraine Headache in one month. Exclusion Criteia: Patient with Epilepsy or Movement Disorders & Appearing of drug side effects. In Intervention Group We've prescribed Topiramate 2mg/kg/day in 2 divided dose (oral) & In Control Group: Propranolol 0.5-1mg/kg/day in 2 divided dose (oral) for 2 months. At the end of the fourth and eighth weeks of treatment response to treatment according to the number, severity and complications are compared Pharmaceutical.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009221808N2**

Registration date: **2010-10-23, 1389/08/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-10-23, 1389/08/01

Registrant information

Name

Ali Abbaskhanian

Name of organization / entity

Mazandaran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences and Health Services

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-03-16, 1389/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Propranolol and Topiramate in Pediatric Migraine prophylaxis

Public title

Comparison the effect of Propranolol and Topiramate in Pediatric Migraine prophylaxis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: 1- Age between 5-15 yr 2- Patient with Common Migraine IHS criteria 3- History of Headache in last 6months 4- No Drug history of Propranolol or Topiromate 5- Discontinuation of other prophylactic drugs one month prior to study 6- At least 2 episode of Migraine Headache in one month. Exclusion Criteria: 1- Contraindications of Propranolol or Topiromate in pre-existing Disease 2- Patient with Epilepsy or Movement Disorders 3- Patient who don't follow up their Treatment

4- Appearing of drug side effects.

Age

From **5 years** old to **15 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Mazandaran University of Medical Sciences and Health Services

Street address

Imam Sq, Joybar 3way, Start of valiye asr highway

City

Sari

Postal code

Approval date

2010-10-06, 1389/07/14

Ethics committee reference number

89-92

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura [common migraine]

Primary outcomes

1

Description

Number of Migraine Headache episode

Timepoint

Before intervention, 4 & 8 weeks after intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Nausea & Vomiting

Timepoint

4 & 8 weeks after beginning of treatment

Method of measurement

Questionnaire

2

Description

Weight loss

Timepoint

4 & 8 weeks after beginning of treatment

Method of measurement

Questionnaire

3

Description

Drowsiness

Timepoint

4 & 8 weeks after beginning of treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

In Intervention Group: Topiramate 2mg/kg/day in 2 divided dose (oral)

Category

Treatment - Drugs

2

Description

In Control Group : Propranolol 0.5-1mg/kg/day in 2 divided dose (oral)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bouali Sina Hospital - Pediatric Department

Full name of responsible person

Street address

City
Sari

2

Recruitment center

Name of recruitment center
Tooba Pediatric Clinic
Full name of responsible person
Street address
City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Center of Mazandaran University of Medical Sciences and Health Services
Full name of responsible person
Dr. Ahmad Ali Enayati
Street address
Moalem sq. Sari
City
Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Center of Mazandaran University of Medical Sciences and Health Services

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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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