Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Mazandaran University of Medical Sciences
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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
Questionnarie

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 - Pediateric 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 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