

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparison of prophylactic efficacy of propranolol and pregabalin in headache control of 3 - 15 years old children with migraine in Mofid children hospital

Protocol summary

Summary

This is a scientific study to answer the question of whether the drugs are effective Pregabalin and propranolol in preventing migraines? Is there any difference between them? In this study, 96 children three to fifteen years coming to Mofid nervous clinic that visit the International Headache Society criteria for migraine diagnosis enrolled in this study and randomly divided into two 48 children groups, who randomly treated with pregabalin or propranolol and 8 weeks later the frequency, severity and duration of headache evaluated and compared in these two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012090910508N1**

Registration date: **2012-10-16, 1391/07/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-10-16, 1391/07/25

Registrant information

Name

MohammadKazem Bakhshandeh Bali

Name of organization / entity

Shahid Beheshti medical university

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Children neurology research center of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of prophylactic efficacy of propranolol and pregabalin in headache control of 3 - 15 years old children with migraine in Mofid children hospital

Public title

Comparison of prophylactic efficacy of propranolol and pregabalin in headache control of children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Children 3-15 years with migraine, coming to Mofid Children's Hospital, according to the International Headache Society criteria for migraine diagnosis Exclusion criteria: History of anticonvulsant hypersensitivity

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 96

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti university Of Medical Sciences

Street address

Velenjak , Tehran

City

Tehran

Postal code

Approval date

2011-12-25, 1390/10/04

Ethics committee reference number

89-01-146-7555-6806

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Episodic and paroxysmal disorders

Primary outcomes

1

Description

Headache

Timepoint

1 and 3 months later

Method of measurement

Interview

Secondary outcomes

empty

Intervention groups

1

Description

We evaluate 96 children 3 to 15 years old coming to Mofid Children Hospital with complaint of headache who after history taking and examination the diagnosis established as migraine and hypersensitivity to anticonvulsants ruled out. Children randomly divided into two groups (1 and 2). We treat children of group 1 with tablet of propranolol (10 to 20 miligram a day) used oral for at least 8 weeks and after 8 weeks since propranolol starting ,we compare the frequency , severity and period of headache in this group with group 2.

Category

Treatment - Drugs

2

Description

We evaluate 96 children 3 to 15 years old coming to Mofid Children Hospital with complaint of headache who after history taking and examination the diagnosis established as migraine and hypersensitivity to anticonvulsants ruled out. Children randomly divided into two groups (1 and 2). We treat children of group 2 with capsule of pregabalin(50 to 75 miligram a day) used oral for at least 8 weeks and after 8 weeks since propranolol starting ,we compare the frequency , severity and period of headache in this group with group 1.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric neurology research center

Full name of responsible person

Doctor Mohammad Kazem Bakhshandeh Bali

Street address

No. 25 , Kamyar Lane , Shariati street , Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Ghofrani

Street address

No. 25 , Kamyar Lane , Shariati street , Tehran

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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
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
Pediatric neurology research center
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