Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 enroled in this study and randomly divited into two 48 childs groups , who randomly treated with pregabalin or propranolol and 8 weeks later the frequency , severity and duration fo headache evaluated and compred in this 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
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Recruitment status

Recruitment complete

Funding source
Children neurology research center of Shahid Beheshti University of Medical Scinces

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 univercity 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
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No. 25 , Kamyar Lane , Shariati street , Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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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

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Person responsible for scientific inquiries

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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