Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Comparison of Pregabalin and Cinnarizine on prophylactic treatment of children with migraine

Protocol summary

Study aim
Comparison of Pregabalin and Cinnarizine on prophylactic treatment of children with migraine

Design
A clinical trial with parallel groups, double-blinded, randomized (permuted block randomization), phase 3 on 74 children with migrane, using www.sealedenvelope.com for randomization.

Settings and conduct
This study is conducted in Rasool Akram Hospital. Children with migraine are randomly assigned into two groups. In the first group, children take Pregabalin oral capsule. In the second group, children take Cinnarizine tablet. In this study, participants and physicians did not know the type of medication they received.

Participants/Inclusion and exclusion criteria
Inclusion criteria: children aged 6 to 17 years with migraine prophylaxis, Migraine diagnosis based on the criteria of the International Headache Society, which includes cases of migraine without aura (5 attacks), migraine with aura (2 attacks), and each attack lasts 1 to 72 hours, and it is pulsating and severe, and accompanied by symptoms With nausea or vomiting, photophobia, phonophobia, Not taking pregabalin and cinnarizine in the past Exclusion Criteria:Drug Intolerance (symptoms such as diarrhea, nausea and vomiting),anaphylaxis, severe dizziness, excessive sleepiness

Intervention groups
In the first intervention group, a Pregabalin oral capsule 50 mg or 75 (manufactured by Actoverco, Iran)mg was prescribed for weight of less than 30 kg and more than 30kg respectively, one time a day for 3 month. The second intervention group, a Pregabalin oral capsule 25 mg or 50 (manufactured by Amin pharmaceutical, Iran)mg was prescribed for weight of less than 30 kg and more than 30kg respectively, one time a day for 3 month.

Main outcome variables
Frequency of migraine headaches

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230415057911N1**
Registration date: **2023-05-21, 1402/02/31**
Registration timing: **retrospective**

Last update: **2023-05-21, 1402/02/31**
Update count: **0**

Registration date
2023-05-21, 1402/02/31

Registrant information

Name
Mohammad Vafaeeshahi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2304 6253

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vafaeeshahi.m@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-10, 1400/03/20

Expected recruitment end date
2023-03-11, 1401/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of Pregabalin and Cinnarizine on prophylactic treatment of children with migraine

Public title
Comparison of Pregabalin and Cinnarizine on treatment of children with migraine

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Consent of parents and children over 13 years to participate in the study Boys and girls aged 6 to 17 years with migraine prophylaxis Migraine diagnosis based on the criteria of the International Headache Society, which includes cases of migraine without aura (5 attacks), migraine with aura (2 attacks), and each attack lasts 1 to 72 hours, and it is pulsating and severe, and accompanied by symptoms With nausea or vomiting, photophobia, phonophobia Not taking pregabalin and cinnarizine in the past

Exclusion criteria:
Drug Intolerance (symptoms such as diarrhea, nausea and vomiting) anaphylaxis severe dizziness excessive sleepiness

Age
From **6 years** old to **17 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the block randomization with block size of 4. we used www.sealedenvelope.com website to generate random sequences. The the random list were provided to a epidemiologist who had no involvement in the selection of the type of drug. Then subjects were randomly assigned to two groups of Pregabalin and Cinnarizine

Blinding (investigator's opinion)
Double blinded

Blinding description
Patient blinding method: Since pregabalin is a capsule and cinnarizine is a tablet, for the similarity of the shape, we put the cinnarizine tablets into powder and inside the pregabalin capsule cover so that both drugs look the same. Doctor's blinding method: The sealed medicine envelopes were given to a researcher who had no involvement in choosing the type of medicine. After the subjects entered the study and their baseline information was collected by the doctor, he sent them to the researcher to get the medicine, and the researcher gave one of the envelopes to the patients, and after that, it was determined in the sheet kept by the researcher that each What medicine did the patient take.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Next to the Milad Tower, Hemmat Highway, Iran University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2021-05-18, 1400/02/28

Ethics committee reference number
IR.IUMS.FMD.REC.1400.127

Health conditions studied

1

Description of health condition studied
Migraine

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
Frequency of migraine headaches

Timepoint
The beginning of the study, 4, 8 and 12 weeks after the intervention

Method of measurement
Patient's history and notes

Secondary outcomes

1

Description
Severity of migraine headaches
Timepoint
The beginning of the study, 4, 8 and 12 weeks after the intervention
Method of measurement
Based on the Visual Analogue Scale (VAS)

2

Description
The rate of migraine attacks disability
Timepoint
The beginning of the study, 4, 8 and 12 weeks after the intervention
Method of measurement
Based on Pediatric Migraine Disability Assessment (PedMIDAS) tool

Intervention groups

1

Description
The first intervention group: In this group, a Pregabalin oral capsule 50 mg or 75 (manufactured by Actoverco, Iran)mg was prescribed for weight of less than 30 kg and more than 30kg respectively, one time a day for 3 month.
Category
Treatment - Drugs

2

Description
The second intervention group: In this group, a Pregabalin oral capsule 25 mg or 50 (manufactured by Amin pharmaceutical, Iran)mg was prescribed for weight of less than 30 kg and more than 30kg respectively, one time a day for 3 month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool Akram Hospital
Full name of responsible person
Mohammad Vafaee Shahi
Street address
At the corner of the Mansouri St, Niayesh St, Satarkhan St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Reza Falak
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5th Floor of Setad Building, Next to the Milad Tower, Hemmat Highway.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohammad Vafaeeshahi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available