

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 migraine, 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)

Phone

+98 21 2304 6253

Email address

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	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.
Scientific title Comparison of Pregabalin and Cinnarizine on prophylactic treatment of children with migraine	Placebo Not used
Public title Comparison of Pregabalin and Cinnarizine on treatment of children with migraine	Assignment Parallel
Purpose Treatment	Other design features
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	Secondary Ids empty
Age From 6 years old to 17 years old	Ethics committees <u>1</u>
Gender Both	Ethics committee Name of ethics committee Ethics committee of Iran University of Medical Sciences
Phase 3	Street address Next to the Milad Tower, Hemmat Highway, Iran University of Medical Sciences
Groups that have been masked • Participant • Care provider	City Tehran
Sample size Target sample size: 74	Province Tehran
Randomization (investigator's opinion) Randomized	Postal code 1449614535
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	Approval date 2021-05-18, 1400/02/28
Blinding (investigator's opinion) Double blinded	Ethics committee reference number IR.IUMS.FMD.REC.1400.127
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	Health conditions studied <u>1</u> Description of health condition studied Migraine ICD-10 code G43 ICD-10 code description Migraine
	Primary outcomes <u>1</u> 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 Vafae Shahi

Street address

At the corner of the Mansouri St, Niayesh St, Satarkhan St.

City

Tehran

Province

Tehran

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1445613131

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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

Street address

5th Floor of Setad Building, Next to the Milad Tower, Hemmat Highway.

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falak.r@iums.ac.ir

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

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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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