

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Cinnarizine versus placebo in pediatric migraine prophylaxis

Protocol summary

Summary

Headaches are common in children and migraine is the most frequent type of recurrent headache; to avoid analgesic overuse and to help the child resume normal activity, preventive pharmacological treatment should be administered. This study is double blind clinical trial. Patients of study: children who have diagnostic criteria for pediatric migraine; children who meet inclusion criteria assigned randomly into two groups. The frequency and intensity of headaches evaluated and documented before starting treatment. First group give Cinnarizine and other group receive placebo. This phase lasted 12 weeks and the response to medications were evaluated and documented monthly.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107216907N2**
Registration date: **2013-01-15, 1391/10/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-15, 1391/10/26

Registrant information

Name

Mahmoudreza Ashrafi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Cinnarizine versus placebo in pediatric migraine prophylaxis

Public title

Efficacy of cinnarizine in the prophylaxis of migraine headache

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1. Patients with migraine (with or without aura), diagnosed according to the International Headache society criteria. 2. Patients who had one or more migraine attack per week ; or sever dysfunction in daily and school activities during prospective baseline phase. 3. Headaches must not relate to any known structural brain lesion or other systemic conditions.

Exclusion criteria: 1. Chronic headache, complications of migraine or other migraine variant. 2. Children and adolescents with Focal neurologic deficit. 3. History of diagnosed sensitivity to cinnarizine . 4. Patients who showed sever adverse effect to the study treatment drugs (in the double-blind phase of the study). 5. Serious comorbidities (hepatic, renal, cardiovascular or thyroid disease). 6. Patients who took prophylactic therapy for migraine within 4 weeks before study.

Age

From **5 years** old to **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **68****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences Ethics Committee

Street address

Keshavarz blv., Ghods avenue, ethic committee of tehran university of medical science

City

Tehran

Postal code**Approval date**

2012-07-18, 1391/04/28

Ethics committee reference number

91-02-54-18168

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 headache

Timepoint

monthly

Method of measurement

questionnaire

2**Description**

severity of headache

Timepoint

monthly

Method of measurement

questionnaire(VAS)

3**Description**

duration of attack

Timepoint

monthly

Method of measurement

questionnaire

Secondary outcomes**1****Description**

adverse effects of cinnarizine

Timepoint

each time during the study

Method of measurement

ask from participants and parents

Intervention groups**1****Description**

cinnarizine tablet 0.6 - 1.5 mg/kg for patient weight under 30 kg and 50mg daily for patient greater than 30kg (3 months) .

Category

Prevention

2**Description**

placebo tablet 0.6 - 1.5 mg/kg for patient weight under 30kg and 50mg for patient greater than 30kg ,daily, (3 months)

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Children`s medical centre

Full name of responsible person

Dr. Mahmoodreza Ashrafi & Dr. Mansooreh Toghae

Street address

Children`s medical centre- dr gharib avenue

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mrs. Rostamabadi

Street address

Poorsina avenue, Keshavarz blv.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Soodeh Salehi

Position

MD, resident of pediatrics

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mahmoodreza Ashrafi

Position

Proffesor of pediatric neurology

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Soodeh Salehi

Position

MD, resident of pediatrics

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Web page address**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