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
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran Univercity 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

Efficasy 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 commitee 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.
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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
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Person responsible for updating data

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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