

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of propranolol plus cinnarizine and propranolol plus placebo in control of migraine headaches in children attending Imam Reza clinic in Shiraz.

Protocol summary

Study aim

To compare efficacy of cinnarizine + propranolol and placebo + propranolol in control of migrainous headaches in children attending Imam Reza clinic, Shiraz, 2018

Design

Two arm parallel group double-blind randomised placebo-controlled single center trial , phase:3 , sample size :106(53 patients in each group)

Settings and conduct

Participants are 6-14 years old children with migraine who attend an outpatient clinic in Shiraz. Patients, physicians and staff nurses are unaware of the type of received intervention. Just the project statistician is aware of the groups' codes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Every child with a diagnosis of migraine (according to international headache society) 2- At least 4 episodes of migraine attacks per month. 3- The age range 6 to 14 years. 4- A migraine headache with or without aura. 5- The patient has not used any drug for prevention of migraine headaches during last month. 6- Parents agree and sign informed written consent form. Exclusion criteria: 1- Age less than 6 or more than 14 years. 2- The patient affected by other forms of migraine headache(variant migraine) 3- The patient has focal neurologic signs or there is radiologic findings in brain imaging. 4- There is a serious comorbidity. 5- There are other systemic diseases. 6- Inability to participate in the study. 7- Use of drugs for preventive measures during last month(at enrollment) 8- A contraindication to use of cinnarizine or propranolol(such as asthma or heart block) 9- Parents refuse to sign an informed consent form.

Intervention groups

Intervention group receive propranolol + cinnarizine for 8 weeks and control group receive propranolol + placebo

for 8 weeks.

Main outcome variables

Frequency and severity of migraine headaches

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180724040576N1**

Registration date: **2018-11-08, 1397/08/17**

Registration timing: **prospective**

Last update: **2018-11-08, 1397/08/17**

Update count: **0**

Registration date

2018-11-08, 1397/08/17

Registrant information

Name

Pegah Katibeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4298

Email address

Katibeh_p@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of propranolol plus cinnarizine and propranolol plus placebo in control of migraine headaches in children attending Imam Reza clinic in Shiraz.

Public title

Effect of cinnarizine in control of pediatric migraine

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Every child with a diagnosis of migraine (according to international headache society) There must be at least 4 episodes of migraine attacks per month. The age range of 6 to 14 years. A migraine headache with or without aura. The patient has not used any drug for preventing migraine headaches during last month Parents agreement and sign informed written consent form.

Exclusion criteria:

The patient affected by other forms of migraine headache (variant migraine). The patient has focal neurologic signs or radiologic findings in brain imaging. There is a serious comorbidity. There are other systemic diseases. Inability to participate in the study. Use of drugs for preventing attacks during last month A contraindication to use of cinnarizine or propranolol (such as asthma or heart block).

AgeFrom **6 years** old to **14 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **106****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, patients are assigned into two groups by simple random sampling procedure. A number or code is devoted to each patient. Codes are produced by statistician using digit random tables. Codes are not deciphered till the end of study. when a patient is found eligible by pediatric neurologist, he/she is referred to staff nurse, and after obtaining informed consent form, and a code from statistician, the drug package is given to the parents .

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, physicians and staff nurses are unaware of the type of treatments received. Just the project statistician is aware of the codes.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shiraz Medical School

Street address

Setad square, Zand avenue

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2018-01-15, 1396/10/25

Ethics committee reference number

IR.SUMS.MED.REC.1396.123

Health conditions studied**1****Description of health condition studied**

Pediatric migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes**1****Description**

Frequency of migraine headaches

Timepoint

Before intervention and 2,4,8 weeks after intervention

Method of measurement

Frequency of headaches will be recorded daily by the parents in a timetable.

2**Description**

Severity of migraine headaches

Timepoint

Before intervention and 2,4,8 weeks after intervention

Method of measurement

Severity of headaches will be measured by Visual Analog Scale

Secondary outcomes

empty

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

Intervention group: Cinnarizine(37.5 mg for children 4-11 years of age and 50 mg for children 12-16 years of age, once daily) and Propranolol (1 mg /kg body weight, once daily). Duration of treatment is 8 weeks.

Category

Treatment - Drugs

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

Imam Reza Clinic

Full name of responsible person

Pegah Katibeh

Street address

Imam Reza Clinic, Pediatrics Clinic, Namazi Square

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

Shiraz University of Medical Sciences

Full name of responsible person

Doctor Yoonas Ghasemi

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

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Pegah Katibeh

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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

Shiraz University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Rozita Bakhshizadeh Shirazi
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Resident of pediatrics
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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