Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of propranolol plus cinarizine 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 cinarizine 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).
Age
From **6 years** old to **14 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target 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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71348714737
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+98 71 3212 7522
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Doctor Yoones Ghasemi
Street address
7th floor, Shiraz University of Medical Sciences, Zand avenue
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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

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Other areas of specialty/work

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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

Position
Resident of pediatrics

Latest degree
Medical doctor

Other areas of specialty/work
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