Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness of Cyproheptadine on paroxysmal short-time headache in children between 2 to 15 years of age: A single-arm clinical trial

Protocol summary

Study aim

To determine the effectiveness of Cyproheptadine on paroxysmal short-time headaches in children aged 2 to 15 years referred to Imam Hossein Hospital in Isfahan in 2021-2022

Design

A non-randomized, single-arm, non-blinded clinical trial

Settings and conduct

All patients will be initially evaluated, including physical examinations, EEG, and neuroimaging tests. After entering the study, a pre-designed checklist will be used for initial data collection, including demographic information, severity and frequency of headache, onset of symptoms, duration of attacks, accompanying symptoms, and history of drug side effects. After providing the necessary training to the parents, they are asked to record the headaches accurately in terms of severity, duration, and count each day. During the study period (three months), patients will be visited on a monthly basis and any drug side effects will be recorded by a checklist.

Participants/Inclusion and exclusion criteria

Children aged 2 to 15 years who diagnose with episodic paroxysmal hemicrania according to ICHD-3 criteria at the neurology clinic of Imam Hossein Hospital in Isfahan from 1400 to 1401 will be included. Patients who have other causes for their headache (such as epilepsy etc.), who are taking medication for their headache, who are allergic to Cyproheptadine or other similar medications, or who have another severe illness that make them unable to record headache events will not enter the study.

Intervention groups

Cyproheptadine is available in the form of 4 mg tablets and 2 mg in 5 ml syrup. In this study, the dose will be 0.2 to 0.4 mg per kilogram of child weight prescribed in two divided doses. Also, necessary recommendations will be made about the factors that may increase the severity and frequency of headaches, such as dietary, physical, and psychological causes.

Main outcome variables

Severity, duration, and frequency of headaches

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190208042654N5**
Registration date: **2022-02-22, 1400/12/03**
Registration timing: **prospective**

Last update: **2022-02-22, 1400/12/03**
Update count: **0**

Registration date

2022-02-22, 1400/12/03

Registrant information

Name

Vahid Mansouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of Cyproheptadine on paroxysmal short-time headache in children between 2 to 15 years of age: A single-arm clinical trial

Public title
Evaluation of the effectiveness of Cyproheptadine on paroxysmal short-time headache in children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children with 2 to 15 years of age Children with episodic paroxysmal hemicrania referred to neurology clinic whose disease has been definitively diagnosed according to the ICHD criteria. Number of attacks of equal or more than once a week
Exclusion criteria:
Patients' unwillingness to cooperate during the study Severe and uncontrollable side effects of cyproheptadine If, based on possible laboratory or imaging findings, a diagnosis other than episodic paroxysmal hemicrania is made during the study Epilepsy or epileptic headaches Existence of structural anomalies in MRI imaging History of allergies to similar drugs Inability to record data on the number, duration, and severity of headaches Taking a prophylactic drug other than Cyproheptadine Severe psychiatric problems such as depression or ADHD
Age
From **2 years** old to **15 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezar Jarib Ave
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2022-02-21, 1400/12/02
Ethics committee reference number
IR.MUI.MED.REC.1400.819

Health conditions studied

1

Description of health condition studied
Episodic Paroxysmal hemicrania
ICD-10 code
G44.03
ICD-10 code description
Episodic paroxysmal hemicrania

Primary outcomes

1

Description
Frequency, duration, and severity of headache attacks and drug side effects
Timepoint
before intervention and each month after intervention
Method of measurement
Checklist includes measuring the number of attacks per week, the duration of attacks in form of minutes and its severity according to the VAS criteria and the occurrence of known side effects

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Cyproheptadine 0.2 to 0.4 mg per kg bodyweight of the child is given in two divided doses for the child. Cyproheptadine is available in the form of 4 mg tablets and 2 mg syrup in 5 ml. These pills are purchased domestically from Jalinus pharmaceutical company and are prescribed to all patients from the same drug brand.

In addition to prescribing medication to all patients, the necessary recommendations will be made about the factors that may increase the severity and frequency of headaches, such as dietary, physical, and psychological causes.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Hossein Hospital
Full name of responsible person
Mohammad Reza Zolfaghari
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Emam Khomeini Ave
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8195163381
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zolfaghari.mohammadreza@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Mansour Siavash
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Jafar Nasiri
Position
Assistant Professor
Latest degree
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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