Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effectiveness of Cinnarizine V/S Topiramate in migraine prophylaxis of children referred to pediatric neurology clinic

Protocol summary

Study aim
Comparing the effectiveness of Cinnarizine with Topiramate in the prophylaxis of migraine in children

Design
A clinical trial with two parallel groups, randomized on 60 patients

Settings and conduct
Children with migraine who need to receive prophylactic treatment (occurrence of one or more headaches per week during the past 6 months, occurrence of intolerable headaches in the past 6 months) and the occurrence of headaches that have caused a disturbance in the person's life) referring to children's neurology clinics of Urmia University of Medical Sciences will be included in the study.

Participants/Inclusion and exclusion criteria
To confirm the diagnosis of migraine, the need for prophylactic treatment and the age of 6-15 years. Patients with advanced migraine who need drugs other than painkillers, previous history of receiving prophylactic treatment, abnormal brain and nerve imaging, and special conditions such as seizures, epilepsy, or the presence of contraindications to cinnarizine and topiramate will be excluded from the study.

Intervention groups
Children will be divided into two general treatment groups with cinnarizine and topiramate and will be treated for 12 weeks according to the time of entering the study in blocks of 5 people and by block randomization method. 6-12-year-old patients in the cinnarizine group will be treated with 25 mg daily. Patients aged 6-15 years in the topiramate group will also be treated with 25 mg daily.

Main outcome variables
the average number of headaches per week and the quality of headache (mild, moderate, severe) based on the severity of the headache per week and drug-related complications such as nausea, vomiting, sleepiness, etc.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221108056444N1**
Registration date: **2023-02-12, 1401/11/23**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-12, 1401/11/23**
Update count: **0**

Registration date
2023-02-12, 1401/11/23

Registrant information

Name
aisan abazarlou

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 3625 8305

Email address
draisanabazarlou@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2023-06-21, 1402/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the effectiveness of Cinnarizine V/S Topiramate in migraine prophylaxis of children referred to pediatric neurology clinic

Public title
Comparison of the effectiveness of Cinnarizine V/S Topiramate in migraine prophylaxis of children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children with migraine The need for prophylactic treatment Age 6-15 years
Exclusion criteria:
Patients with advanced migraine who need drugs other than painkillers Previous history of receiving prophylactic treatment Abnormal brain and nerve imaging and special conditions such as seizures, epilepsy or the presence of contraindications for the use of cinnarizine and topiramate
Age
From **6 years** old to **15 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blocked randomization method will be used for randomization. In this way, blocks of size 6 (AAABBB) will be determined first and all possible states of this combination will be listed. For each one, a specific code will be given and in Further, according to the size of the blocks (6) and the sample size (60), the number of 10 blocks will be selected by a simple random method. The entire randomization process will be done using the RANDOM ALLOCATION software.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences
Street address
Serah Kashani, Motahari Hospital
City
Urmia
Province
West Azarbaijan
Postal code
57146154637
Approval date
2022-10-22, 1401/07/30
Ethics committee reference number
IR.UMSU.REC.1401.277

Health conditions studied

1

Description of health condition studied
Migraine
ICD-10 code
G43
ICD-10 code description
Migraine

Primary outcomes

1

Description
Headache
Timepoint
At the beginning of the study, 1, 3, 6, 9, and 12 weeks after the start of treatment
Method of measurement
Migraine Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The intervention in the present study will be the administration of two drugs, cinnarizine and topiramate. The drug cinnarizine in the form of tablets with a dose of 25 mg will be administered daily in the morning for 12 weeks.
Category
Treatment - Drugs

2

Description
The drug topiramate in the form of tablets with a dose of 25 mg in the morning to It will be prescribed for 12 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tadbir Clinic
Full name of responsible person
Aisan Abazarlou
Street address
Motahari Hospital, Kashani Street
City
Urmia
Province
West Azarbaijan
Postal code
5714615463
Phone
+98 44 3224 1967
Email
draisanabazarlou@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Saber Gholizadeh
Street address
Motahari Hospital, Kashani Street
City
Urmia
Province
West Azarbaijan
Postal code
5714615463
Phone
+98 44 3224 1967
Email
draisanabazarlou@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Aisan Abazarlou
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Motahari Hospital, Kashani Street
City
Urmia
Province
West Azarbaijan
Postal code
57146154637
Phone
+98 44 3223 7077
Email
draisanabazarlou@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Aisan Abazarlou
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
No.30 , Adili Alley , Pasdaran Alley , Valiasr Blv , khoy City , West azerbayjan
City
Urmia
Province
West Azarbaijan
Postal code
5815614879
Phone
+98 44 3625 8305
Fax
Email
draisanabazarlou@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Aisan Abazarlou

Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Motahari Hospital, Kashani Street
City
Urmia
Province
West Azarbaijan
Postal code
57146154637
Phone
+98 44 3223 7077
Email
draisanabazarlou@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data may be published
When the data will become available and for how long
Since 2023
To whom data/document is available
Access for all
Under which criteria data/document could be used
Doctors and researchers
From where data/document is obtainable
Researcher , 09149491518
What processes are involved for a request to access data/document
Contact with the researcher, the reason for the need to receive data
Comments