

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 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

aيسان 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 azerbaijan

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