Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the therapeutic effects of using single-dose and twice-daily topiramate for migraine prophylaxis in children aged 5 to 18 years referred to Tehran Children's Medical Center Hospital

Protocol summary

Study aim

Evaluation of the effectiveness of single-dose and twice-daily topiramate in reducing the severity, duration, and frequency of migraine attacks in children referred to Tehran Children's Medical Center Hospital

Design

Randomized controlled clinical trial with parallel groups on 70 patients. Randomization is done using Block Randomization.

Settings and conduct

In Patients referred to the Children's Medical Center in Tehran, demographic findings, assessment of the effectiveness of the drug in prophylaxis, frequency and severity of attacks, duration of migraine attacks, disability due to migraine, and side effects of the drug used will be asked and noted in the patient's clinic file. Symptoms related to the severity, frequency, and duration of headaches will be recorded every 3 months during periodic patient visits.

Participants/Inclusion and exclusion criteria

the inclusion criteria encompassed children aged 5 to 18 years diagnosed with migraine according to the International Classification of Headache Disorders, 3rd edition (ICHD-3), candidates for prophylactic treatment with a minimum of two migraine attacks per month, and informed consent obtained from their parents or legal guardians. Exclusion criteria included the presence of other systemic diseases, use of medications for migraine prevention in the past three months, known hypersensitivity to topiramate, and inability to adhere to regular follow-up assessments.

Intervention groups

بیمار مبتلا به بیماری میگرن در طول ۶ ماه مورد مطالعه قرار ۷۰ میگیرند. این بیماران به صورت تصادفی به دو گروه ۳۵ نفری تقسیم می شوند و برای دسته اول داروی توپیرامات به صورت تک دوز و برای دسته دوم داروی توپیرامات به صورت دو دوز در روز (BD) تجویز می گردد. این بیماران تحت درمان پروفیلاکسی با توپیرامات با دوز ماکزیموم دوز ۱۰۰ میلی گرم در روز قرار خواهند ۲mg/kg/day گرفت.

Main outcome variables

Severity, frequency, duration, and headache-related disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250508065645N1**
Registration date: **2025-05-16, 1404/02/26**
Registration timing: **prospective**

Last update: **2025-05-16, 1404/02/26**
Update count: **0**

Registration date

2025-05-16, 1404/02/26

Registrant information

Name
Sina Fathi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 2238 1781
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sina_fth74@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-22, 1404/04/01

Expected recruitment end date

2025-12-22, 1404/10/01

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

Scientific title
Comparison of the therapeutic effects of using single-dose and twice-daily topiramate for migraine prophylaxis in children aged 5 to 18 years referred to Tehran Children's Medical Center Hospital

Public title
Single-dose topiramate in migraine prophylaxis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
The inclusion criteria for the study are children aged 5 to 18 years diagnosed with migraine according to the International Classification of Headache Disorders, 3rd edition (ICHD-3) , candidates for prophylactic treatment who experienced a minimum of two migraine attacks per month , and obtained informed consent from their parents or legal guardians to participate in the study
Exclusion criteria:
Age
From **5 years** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study randomization was employed to randomly assign participants to treatment groups. This method aids in maintaining group balance and controlling confounding variables by dividing participants into homogeneous blocks and randomizing within each block
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 Tehran University of Medical Sciences
Street address
Central Building of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
461884513
Approval date
2025-04-19, 1404/01/30
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1404.045

Health conditions studied

1

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

Primary outcomes

1

Description
Headache frequency, headache severity, headache duration, headache-related disability, side effects
Timepoint
At the beginning of the study, 3 months and 6 months after taking the medication
Method of measurement
History, Verbal Pain Scale, Visual Analogue Scale, Pediatric Migraine Disability Assessment (PedMIDAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the present study the calculated therapeutic dose of topiramate for pediatric patients was based on guidelines from the American Academy of Neurology (AAN) and the American Headache Society (AHS), which recommend a dose of 2 mg/kg/day with a maximum of 100 mg/day. Topiramate was initiated at a dose of 1 mg/kg/day for participants and, if necessary, titrated according to a predefined schedule to reach the

optimal dose.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

مرکز طبی کودکان تهران

Full name of responsible person

Dr Mahmoudreza Ashrafi

Street address

No. 62. , Dr Gharib St., Keshavarz Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Ramin Kordi

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Sixth Floor, Central Building of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Sina Fathi

Position

Resident of Pediatrics

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Fax

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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