

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 تجویز می (BD) دسته دوم داروی توپیرامات به صورت دو دوز در روز گردد. این بیماران تحت درمان پروفیلاکسی با توپیرامات با دوز

۲mg/kg/day ۱۰۰ میلی گرم در روز قرار خواهند 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)

Phone

+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
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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
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Sixth Floor, Central Building of Tehran University of
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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
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Other areas of specialty/work
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Fax**Email**

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