Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effectiveness of magnesium oxide and riboflavin on the prevention of migraine attacks in children : A single-blind clinical trial study

Protocol summary

Study aim

Determining and comparing the effectiveness of magnesium oxide and riboflavin on preventing migraine attacks in children referred to Imam Ali Clinic in Shahrekord

Design

A phase III randomized, single-blind, parallel-group clinical trial. For this purpose, 70 identical cards were prepared, with the letter 'A' printed on 35 of them and the letter 'B' printed on the other 35. These cards were placed shuffled in a bag. For each patient, one card was drawn at random. The letter printed on the drawn card determined the patient's treatment group.

Settings and conduct

The study will be conducted at the Children's Clinic of Shahrekord . After patient selection, randomization and blinding will be performed using the method described above.

Participants/Inclusion and exclusion criteria

Inclusion criteria included: Children aged 6 to 12 years with moderate to severe migraine headache with or without aura Written informed consent to participate in the study No use of medications that interact with magnesium oxide or riboflavin No severe neurological disorders or epilepsy No hepatic, renal, gastrointestinal, cardiovascular, or metabolic disorders No history of tension headaches No history of sensitivity to magnesium oxide or riboflavin No history of renal failure Exclusion criteria: Any sensitivity to magnesium oxide or riboflavin during the study Patient unwillingness to continue participating in the study

Intervention groups

A: Amitriptyline tablet (0.5-1 mg/kg), one tablet daily with a maximum daily dose of 50 mg. Group B: Will be treated with Magnesium Oxide tablet (9 mg/kg once daily) + Riboflavin tablet (100 mg once daily)for 8 weeks.

Main outcome variables

Migraine headache onset time Family history of migraine Frequency of migraine headache attacks Duration of each episode Headache severity Nausea Vomiting Dizziness Migraine Disability Assessment Questionnaire (PedMIDAS) Drug side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251020067696N1**
Registration date: **2025-11-26, 1404/09/05**
Registration timing: **retrospective**

Last update: **2025-11-26, 1404/09/05**
Update count: **0**

Registration date

2025-11-26, 1404/09/05

Registrant information

Name

Mehran Ansarian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3110 7207

Email address

ansarian.m157@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-06, 1404/08/15

Expected recruitment end date

2025-11-21, 1404/08/30

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

Scientific title
Comparing the effectiveness of magnesium oxide and riboflavin on the prevention of migraine attacks in children : A single-blind clinical trial study

Public title
Comparing the effectiveness of magnesium oxide and riboflavin on the prevention of migraine attacks in children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 6 to 12 years with moderate to mild migraine headaches with or without aura Written informed consent to participate in the study Avoid taking medications that interact with magnesium oxide or riboflavin. No severe neurological disorders or epilepsy No hepatic, renal, gastrointestinal, cardiovascular, or metabolic disorders No tension headaches No history of sensitivity to magnesium oxide or riboflavin No renal failure
Exclusion criteria:
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
For this purpose, 70 identical cards, 35 of which have the letter A and 35 of which have the letter B, are placed in a jumbled envelope and one card is randomly drawn for each patient. The letter on the card will indicate the patient's treatment group.
Blinding (investigator's opinion)
Single blinded
Blinding description
For this purpose, 70 identical cards, 35 of which have the letter A and 35 of which have the letter B, are placed in a jumbled envelope and one card is randomly drawn for each patient. The letter on the card will indicate the patient's treatment group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Ethics Committee of Shahrekord University of Medical Sciences, Hajar Hospital Clinical Research
Street address
parastar st, Hajar Hospital
City
shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8817913645
Approval date
2025-01-19, 1403/10/30
Ethics committee reference number
IR.SKUMS.MED.REC.1403.103

Health conditions studied

1

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

Primary outcomes

1

Description
Average duration of migraine attacks
Timepoint
At the beginning of the study (before starting the intervention) and two months after treatment (end of the study).
Method of measurement
Study data will be recorded using a researcher-made checklist that includes: age, sex, body mass index, migraine with and without aura, months since migraine onset, family history of migraine, and the average severity, frequency, and duration of headaches, dizziness, migraine disability criteria, along with the Pediatric Migraine Disability Assessment (PedMIDAS) questionnaire.

Secondary outcomes

1

Description
Time of migraine headache onsetFamily history of migraineFrequency of migraine headache attacksDuration of each episodeHeadache

severityNauseaVomitingDizzinessMigraine Disability Assessment Questionnaire (PedMIDAS)Drug side effects

Timepoint

در ابتدای مطالعه (قبل از شروع مداخله) و دو ماه پس از درمان (انتهای مطالعه))

Method of measurement

Study data will be recorded using a researcher-made checklist that includes: age, sex, body mass index, migraine with and without aura, months since migraine onset, family history of migraine, and the average severity, frequency, and duration of headaches, dizziness, migraine disability criteria, along with the Pediatric Migraine Disability Assessment (PedMIDAS) questionnaire.

Intervention groups

1

Description

Intervention group: Treatment with Magnesium Oxide tablet (9 mg/kg once daily)(39) + Riboflavin tablet (100 mg once daily)(30) for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

شهرکرد،کلینیک امام علی

Full name of responsible person

Mehran Ansarian

Street address

Nurse Street, Hajar Hospital

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8817913645

Phone

+98 913 882 5092

Email

ansarian.m157@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Soleimani, Vice Chancellor for Research and Technology

Street address

Nurse Street, Hajar Hospital

City

shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8817913645

Phone

+98 913 882 5092

Email

ansarian.m57@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

mehran ansarian

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Nurse Street, Hajar Hospital

City

shahrekord

Province

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Postal code

8817913645

Phone

+98 913 882 5092

Email

ansarian.m157@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Mehran Ansarian

Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
No. 10, Amin 12 Alley, Iman Street, West Mirabd District, Shahrekord
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8817913645
Phone
+98 38 3110 7207
Fax
Email
ansarian.m157@gmai.com

Person responsible for updating data

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Mehran Ansarian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
No. 10, Amin 12 Alley, Iman Street, West Mirabd District, Shahrekord
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8817913645
Phone
+98 38 3110 7207
Fax
Email
ansarian.m157@gmai.com

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