Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the prophylactic effect of magnesium versus placebo in reduction of frequency, severity and duration of migraine headaches in children aging 6-18 years old

Protocol summary

Study aim
In this study, we intend to evaluate the effect of magnesium + propranolol versus placebo + propranolol in pediatrics afflicted with migraine.

Design
A randomized double-blind placebo-controlled phase 3 clinical trial with parallel design. 140 patients are randomized to 2 groups and take the aforementioned medications for 3 months and complete a migraine diary. randomization is done using random table.

Settings and conduct
The study is performed in Pediatrics neurology unit of Imam Reza clinic in Shiraz city, a governmental facility. eligible patients are randomized and provided with appropriate medications with identical shapes and packaging and, followed up for 3 months. studying physicians and patients are blind to the study group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children with 6-18 years of age and weights less than 90 Kg, having migraine diagnosed according to IHSC-3 criteria with at least 4 migraine attacks per month or 8 days-of-headache per month in the past month. Exclusion Criteria: Coexistence of another type of headache; having migraine headaches or using analgesics on at least 15 days per month; history of epilepsy or neurological comorbidity; mental retardation; Addiction; magnesium contraindications; propranolol contraindications; history of using migraine prophylaxis medications or magnesium supplements in the past month; history of psychiatric disorders; patient's poor medication compliance; Illiteracy of the patient and family

Intervention groups
Half of the patients take Magnesium Oxide 10 mg/kg/day and another half take identical placebo; in addition, both groups also receive Propranolol 0.5 mg/kg/day. after the first visit, patients are evaluated 4 weeks and 12 weeks after the initiation.

Main outcome variables
Amount of reduction in frequency of migraine attacks is the primary outcome of the study.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221115056506N1**
Registration date: **2023-02-06, 1401/11/17**
Registration timing: **prospective**

Last update: **2023-02-06, 1401/11/17**
Update count: **0**

Registration date
2023-02-06, 1401/11/17

Registrant information

Name
Mohammad Akrami

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-09, 1401/11/20

Expected recruitment end date
2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the prophylactic effect of magnesium versus placebo in reduction of frequency, severity and duration of migraine headaches in children aging 6-18 years old

Public title

Evaluation of magnesium effect in treatment of migraine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age from 6 to 18 years old Weight less than 90 Kg Diagnosed as migraine according to IHSC-3 criteria At least 4 migraine attacks in month or 8 days-of-headache during at least 1 month ago

Exclusion criteria:

Coexistence of another type of headache Migrainous headache in at least 15 days per month Using analgesic medications in at least 15 days per month Pregnancy or intention of pregnancy History of epilepsy or other neurological comorbidities Mental retardation defined as IQ<70 Dependency or addiction to pharmaceutical or illicit drugs Magnesium administration contraindications Renal failure History of renal stone Propranolol administration contraindications Cardiac conduction block Bradycardia History of asthma History of hypersensitivity reaction to propranolol Diabetes mellitus Liver insufficiency Myasthenia gravis Psoriasis History of using migraine prophylaxis medications in the past month History of using magnesium supplements in the past month History of psychiatric disorders including depression, mood disorders, anxiety disorders or psychotic disorders History of using anti-depressants, anti-psychotics, mood stabilizers or sedatives Anticipation of patient's poor medication compliance Illiteracy of the patient and family and, inability of filling the diary

Age

From **6 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed via block randomization method comprising 35 blocks of 4 individuals using statistical software and, the random sequence of the study is made beforehand. allocation concealment is ensured by putting unique patient-numbers on medication packets and, delivered to the patient upon entering to the study according to the random sequence while, researcher is unaware of the allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

Initially, informed consent, demographic and baseline information are obtained. Patient and physician are blind to the intervention groups. Patients' allocated groups are written down in a notebook by physician assistant and will be revealed at the end of the study. Randomization is performed by the assistant and medication delivery is done in the clinic by another assistant. Magnesium oxide pills and placebo are given in identical small packets with identical labeling. Propranolol tablets are given in its standard factory-made packages.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand Blvd.

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2022-07-04, 1401/04/13

Ethics committee reference number

IR.SUMS.MED.REC.1401.258

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description
Frequency of migraine attacks per month
Timepoint
At the beginning; then, 4 weeks later; then, 12 weeks after the initiation
Method of measurement
Direct asking of the patient in the first visit; then, using migraine diary in the following visits

Secondary outcomes

1

Description
Severity of pain during migraine attacks
Timepoint
First visit; 4 weeks later; 12 weeks later
Method of measurement
Wong-baker scale

2

Description
Average duration of migraine attacks per month
Timepoint
First visit; 4 weeks later; 12 weeks later
Method of measurement
direct asking and migraine diary

3

Description
Amount of analgesic medications used
Timepoint
First visit; 4 weeks later; 12 weeks later
Method of measurement
direct asking and migraine diary

Intervention groups

1

Description
Intervention group: Magnesium oxide 10 mg/kg in 1 or 2 divided dose for 3 months should be used. Generic Magnesium Oxide 250 mg tablets from Jalinus pharmaceutical company are used. patients are also provided with Propranolol 0.5 mg/kg/day.
Category
Treatment - Drugs

2

Description
Control group: Placebo with complete resemblance to magnesium oxide pills with similar usage order produced by the pharmaceutical laboratory of Shiraz school of pharmacy. patients are also provided with Propranolol 0.5 mg/kg/day.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza clinic in Shiraz
Full name of responsible person
Pegah Katibeh
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahtab Memarpour
Street address
Zand St.
City
Shiraz
Province
Fars
Postal code
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Phone
+98 71 3212 2430
Email
vcrdep@sums.ac.ir
Web page address
https://research.sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Pegah Katibeh
Position
Assistant Professor
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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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
All patients' data would be available after anonymization.
When the data will become available and for how long
Data would be available to public after publication of the article.
To whom data/document is available
Data is only provided for scientific purposes to researchers.
Under which criteria data/document could be used
Data will be available for research purposes.
From where data/document is obtainable
Please contact Dr. Pegah Katibeh or Dr. Mohammad Akrami via Email.
What processes are involved for a request to access data/document
After evaluation of request, data will be provided in fastest time possible and no specific legal pathway is in

consideration.

Comments