# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jul 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**

**Country**
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
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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
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**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
**Latest degree**
Subspecialist
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**
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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**