Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Studying effectiveness of Short Term oral Magnesium supplement Prophylaxis In Menstrually Related Migraine (MRM) in women in reproductive ages : A Randomized Controlled Trial

Protocol summary

Study aim

Evaluate effect of short term oral magnesium prophylaxis on prevention, frequency, intensity, prolongation, amount of analgesic drugs and resulting palliation In Menstrually Related Migraine (MRM) headache attacks.

Design

In this blinded, randomized, concealed clinical trial with a parallel group design patients examine for 3 continuous months in magnesium users and placebo users subgroups.

Settings and conduct

Each qualified patient fill out questionnaire about her MRM headache attacks features in 1 month without any magnesium or placebo usage initially, then a third person divides participants into magnesium and placebo groups randomly (random allocation rule) and also he is the only person who has access to patient's personal information, then he gives out tablets according to each person's group and after passing 3 months he collect questionnaires and records data and reports them anonymously to researcher and analyzer.

Participants/Inclusion and exclusion criteria

Women of reproductive age who have regular menses and affected by Menstrually Migraine, meet the last International Classification of Headache Disorders's (ICHD) criteria for MRM and doesn't fill the exclusion criteria that was named.

Intervention groups

Half of the qualified patients use 375 milligrams oral magnesium (magnesium oxide tablets) and the other half also use placebo tablets which are exactly the same size, smell and color, for 3 continuous Menstrual cycles from fifteenth day of each cycle to the third day of next one.

Main outcome variables

group (magnesium and placebo), age, menstrual cycle length, headache frequency, intensity, prolongation, amount of analgesic drugs and resulting palliation, side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190415043284N1**
Registration date: **2019-08-15, 1398/05/24**
Registration timing: **retrospective**

Last update: **2019-08-15, 1398/05/24**
Update count: **0**

Registration date

2019-08-15, 1398/05/24

Registrant information

Name

pegah Yabande jahrom

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8255

Email address

yabande.p@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-03-16, 1397/12/25

Actual recruitment start date

2019-01-21, 1397/11/01

Actual recruitment end date
2019-04-19, 1398/01/30
Trial completion date
2019-07-21, 1398/04/30

Scientific title
Studying effectiveness of Short Term oral Magnesium supplement Prophylaxis In Menstrually Related Migraine (MRM) in women in reproductive ages : A Randomized Controlled Trial

Public title
Short Term Magnesium Preventation In Menstrually Related Migraine (MRM)
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
patients affected by menstrually related migraine according to 3rd edition of The International Classification of Headache Disorders regular mense
Exclusion criteria:
chronic diarrhea renal failure nephrolithiasis myasthenia gravis patients anti hypertensive drug usage particularly calcium channel blocker users diabetic patients who has insulin resistance state pregnancy or planned pregnancy; ; menstrual migraine [14] breast feeding women non migraine headache psychiatric illness according to DSM5 criteria chronic systemic illness dependence or abuse of drugs intake of antidepressants, neuroleptics, minor or major tranquillizers, drugs used for the treatment of affective disorders (e.g. lithium, carbamazepine), antiepileptics bradrychardia anti coagulant and antiplatelet usage pure menstrually migraine
Age
From **20 years** old to **50 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants assign to comparison groups (allocation sequence) with random allocation rule (a form of restricted randomisation procedures- after sample taking finished, we put magnesium and placebo papers, half and half number in a sortition container and bring them out randomly to make an allocation sequence.) and this allocation conceals by central randomization.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants are unaware of who is receiving the real treatment and by means of a third party who collected data and bring them anonymous to assessor and and analyser blinding done.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences
Street address
No. 3,Mahsa building, Alley 13, Khadem Sadeq Ave., Amir Kabir Blv., shiraz
City
Ahvaz
Province
Khouzestan
Postal code
۷۱۷۸۷۴۴۳۵۹
Approval date
2018-05-05, 1397/02/15
Ethics committee reference number
IR.AJUMS.REC.1397.083

Health conditions studied

1

Description of health condition studied
Menstrually Related Migraine (MRM)
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
headache attacks of menstrually related migraine
Timepoint
4 questionnaires are filled: the first one at the sampling time and 3 others during 3 continuous menstrual cycles which the participant take pills.
Method of measurement
questionnaire

Secondary outcomes

1

Description
headache frequency, intensity, prolongation, amount of analgesic drugs and resulting palliation

Timepoint
4 questionnaires are filled: the first one at the sampling time and 3 others during 3 continuous menstrual cycles which the participant take pills.

Method of measurement
Each questionnaire contains a calendar with blanks to record: the exact date of menstruation starting date, headache days, headache intensity (1 to 10 scale), each headache attack prolongation (hours), number of analgesic pills to pain relief and resulting palliation (describes with excellent, good, intermediate and poor response)

Intervention groups

1

Description
Intervention group: each patient during 3 continuous menstrual cycles, taking one and half (375 milligrams) of 250 miligrames magnesium oxide pills from Jalinous Pharmaceutical company daily and records headaches from 2 days before menstruation up to third day of mens.
Control group: each patient during 3 continuous menstrual cycles, taking one and half of placebo pills daily and records headaches from 2 days before menstruation up to third day of mens.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Golestan hospital

Full name of responsible person
Ehsan Mohammadiani Nejad

Street address
Neurology ward, Golestan hospital, Farvardin Aven., Golestan Blv..

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mohammad Badavi

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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
Ahvaz University of Medical Sciences

Proportion provided by this source
30

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
Ahvaz University of Medical Sciences

Full name of responsible person
Ehsan Mohammadiani Nejad

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Neurology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Data about magnesium prophylaxis effects on menstrually related migraine headaches and its Side effects will share.
When the data will become available and for how long
at least 6 months after the date that results have been published.
To whom data/document is available
researchers who work for universities
Under which criteria data/document could be used
To investigate weak points of this study to obtain and start a new and more useful work
From where data/document is obtainable
Dr Ehsan Mohammadiani Nejad, neurology ward, Ahvaz Jundishapur university of medical sciences
What processes are involved for a request to access data/document
Deliver a request containing exact description of reasons for this request and make a list of the exact data which is needed, to the neurology group. this request will be checked as soon as possible and will be answered.
Comments