Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Effectiveness of Magnesium Oxide and Vitamin C Supplementation in Prevention of Migraine Headaches

Protocol summary

Study aim
prevention
Design
Clinical trial without control group, with parallel groups, single-blind, randomized, 82 patients
Settings and conduct
Location: Hazrat Rasoul Clinic, Shahrekord University of Medical Sciences, Method: 82 patients who met the inclusion criteria and did not meet the exclusion criteria were admitted to the study with consent and were randomly divided into two groups. One group received 250 mg of vitamin C daily for 2 months and the other group received magnesium oxide. The MSQ and Beck Depression Inventory are filled out by patients at the beginning and end of two months. Patients in both groups do not know which medication they are taking.
Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Their age is between 18 and 60 years. 2. According to ICHD-3 International Community Headache criteria, the diagnosis of migraine should be made by a neurologist at least one year in advance. 3. Diagnosis of moderate to severe migraine Exclusion criteria 1. Fever or evidence of infection 2. Simultaneous infection with other headaches 3. A history of major depression 4. Daily use of painkillers 5. Pregnancy or pregnancy intention 6. Having chronic diseases
Intervention groups
Group one: 250 mg magnesium oxide tablets once daily orally for 8 weeks Group 2: Vitamin C supplement tablets of 250 mg once daily orally for 8 weeks
Main outcome variables
The effect of migraine headaches on daily activities based on the MSQ questionnaire Depression score based on Beck Depression Inventory

General information

Reason for update
Regarding the method of blinding the study, after consulting again with the statistical consultant of the project to improve the scientific level of the study, it was decided that the type of randomization method in this two-way trial is blind so that the researcher and patients decide which drug is among the two drugs introduced in The schemes used are uninformed but the clinical caregiver divides and distributes the drugs in similar packages..
Acronym
IRCT registration information
IRCT registration number: **IRCT20201221049787N1**
Registration date: **2021-01-16, 1399/10/27**
Registration timing: **prospective**

Last update: **2021-01-20, 1399/11/01**
Update count: **1**
Registration date
2021-01-16, 1399/10/27

Registrant information
Name
Samira Sourani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 38 3336 4072
Email address
samira.sooraniii95@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-01-20, 1399/11/01
Expected recruitment end date
2021-05-22, 1400/03/01
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Magnesium Oxide and Vitamin C Supplementation in Prevention of Migraine Headaches

Public title

Magnesium Oxide and Vitamin C in Migraine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

According to ICHD-3 standards, the diagnosis of migraine should be made by a neurologist and they should be diagnosed with migraine at least one year before the visit Diagnosis of moderate to severe migraine (which is the number of headache attacks 2-15 times a month or attacks with less intensity and duration that cause the person to be unable to perform daily tasks

Exclusion criteria:

Fever or evidence of infection Simultaneous onset of other headaches such as tension headaches, sinusitis, or substance abuse headaches People with active peptic ulcer and severe gastrointestinal disorders, especially chronic diarrhea History of kidney failure History of diabetes history of major depression History of asthma and heart disease (conduction block and heart failure) Daily use of painkillers Pregnancy or pregnancy intent Having chronic diseases

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization by random number table method: After filling the informed consent of the study participants, patients will be divided into two groups by random number table method and will receive and consume one of the two drugs studied in the plan.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blind blindness: The clinical researcher and the patients participating in the project are not aware of the type of drug used and only the clinical caregiver, knowing the type of drug, distributes it in similar envelopes. It should be noted that the drugs are similar in dose, color and shape. Also, the envelopes are nameless and recognizable only to the clinical caregiver.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

No. 1, First Ave., sourani St., Manzarieh

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815694438

Approval date

2019-07-28, 1398/05/06

Ethics committee reference number

IR.SKUMS.REC.1398.117

Health conditions studied

1

Description of health condition studied

Common Migraines

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura

2

Description of health condition studied

Classic Migraine

ICD-10 code

G43.1

ICD-10 code description

Migraine with aura

Primary outcomes

1

Description

The effect of migraine headaches on daily activities

Timepoint

At the beginning of the study and after eight weeks of medication

Method of measurement

MSQ questionnaire

2

Description
Depression score in Beck questionnaire
Timepoint
At the beginning of the study and after eight weeks of medication
Method of measurement
Beck Depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Magnesium oxide tablets 250 mg once daily orally for 8 weeks
Category
Treatment - Drugs

2

Description
Intervention group: Vitamin C 250 mg tablets once daily orally for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasoul Clinic affiliated to Shahrekord University of Medical Sciences
Full name of responsible person
Dr. Majid Jafari
Street address
Moulavi
City
Shahr e Kord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3226 4833
Email
jafarimd90@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr. Majid Shirvani
Street address
Kashani Blvd., the headquarters of the university
City
Shahr e Kord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3334 9508
Email
src@skums.ac.ir
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
Samira Sourani
Position
Intern
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
No. 1, First Ave., Sourani St., Manzarieh
City
Shahr e Kord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815694438
Phone
+98 38 3336 4072
Email
samira.sooraniii95@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Dr. Majid Jafari

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Neurology

Street address
Hajar Hospital., Parastar St

City
Shahr e Kord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8816754633

Phone
+98 38 3222 5505

Email
jafarimd90@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Samira Soorani

Position
Intern

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

Street address
No 1., First Ave., Sourani St., Manzarieh

City
Shahr e Kord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815694438

Phone
+98 38 3336 4072

Email
samira.sooraniii95@gmail.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