

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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.sooranii95@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

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Chahar-Mahal-va-Bakhtiari

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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

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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

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Majid Jafari

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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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