Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of adding L-carnitine supplement to migraine prophylaxis treatment on the symptoms and signs of migraine headaches.

Protocol summary

Study aim

Investigating the effect of adding L-carnitine supplement to migraine prophylaxis treatment on the symptoms and signs of migraine headaches in patients referred to the neurology clinic of Allameh Bohloul Gonabadi Hospital.

Design

Parallel group, double blind, randomized controlled trial in phase 2 and sample size of 48. Randomization was done using permutation block with size of 4.

Settings and conduct

This interventional study will be conducted as a prospective, Single-center trial. 48 patients with migrain admitted to Bohlool hospital will be selected. All patients who meet the eligibility criteria with informed consent will receive l-carnitin or placebo.The control and intervention groups are marked with two codes A and B, and the outcome evaluation physician and the analyst will not be aware of the nature of these two groups for data analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria :Informed consent, Migraine with or without aura, Having 2 or more migraine attacks per month. Exclusion criteria: Absence of kidney or liver disease, Pregnancy, breastfeeding.

Intervention groups

The intervention group and control group includes patients with migraine. The intervention group was treated for one month with the standard migraine prophylaxis treatment + 500 mg L-carnitine tablets of Kharazmi company, crushed and placed inside the capsule, one daily. In the control group, capsules with the same color and shape as the test group are added once a day to routine migraine prophylaxis treatment for one month.

Main outcome variables

Number of days with moderate to severe headache lasting more than 4 hours or treated with usual treatments, Severity of headache on days with headache,Doses of analgesics and triptans

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200418047116N3**
Registration date: **2023-09-10, 1402/06/19**
Registration timing: **prospective**

Last update: **2023-09-10, 1402/06/19**
Update count: **0**

Registration date

2023-09-10, 1402/06/19

Registrant information

Name

Negar Shafaei bajestani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5723 6833

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of adding L-carnitine supplement to migraine prophylaxis treatment on the symptoms and signs of migraine headaches.

Public title

Investigating the effect of adding L-carnitine supplement to migraine prophylaxis treatment

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Signed informed consent Migraine with or without aura according to the International Classification of Headache Disorders Having 2 or more migraine attacks per month during the past 3 months Migraine onset before age 50 BMI (kg/m2) between 18 and 35

Exclusion criteria:

Absence of kidney disease or reduced kidney function and liver cirrhosis No previous use of L-carnitine No use of ≥ 3 prophylactic medications against migraine during the past 5 years No alcohol or illegal drug addiction Not having asthma or vascular disease, arterial lameness Pregnancy, breastfeeding

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

In the current study, patients with migraine referred to the neurology clinic of Allameh Bohloul Gonabadi Hospital were selected using available sampling technique. If they want to participate in the study and meet the entry criteria, written and informed consent will be obtained from them. Then, in order to assign the patients to two intervention and control groups, he used the method of quadruple permutation blocks in such a way that first six possible states of the blocks (BAAB, ABBA, BABA, BBAA, ABAB, AABB) were listed and to each block one number of One to six will be allocated and will be used for four patients. Then, a number between one and six is randomly selected using the random number table, and then people are assigned to the control group (A) and the intervention group (B) based on the block corresponding to the selected number. It will continue until the end of the sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the intervention group, L-carnitine tablets of 500 mg once a day will be crushed and placed inside the capsule and will be added to the routine migraine prophylaxis treatment. . In the control group, routine prophylaxis treatment and identical placebo are used instead of L-carnitine. People in both the intervention and control groups will receive the necessary training from the researcher about the objectives of the study, the benefits of studying how and how much to consume L-carnitine, the exclusion criteria, and the duration of the intervention. did The control and intervention groups are marked with two codes A and B, and the outcome evaluation physician and the analyst will not be aware of the nature of these two groups for data analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Imam Khomeini Street, Gonabad University of Medical Sciences

City

Gonabad

Province

Razavi Khorasan

Postal code

9691615147

Approval date

2023-01-09, 1401/10/19

Ethics committee reference number

IR.GMU.REC.1401.194

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43.9

ICD-10 code description

Migraine, unspecified

Primary outcomes

1

Description
Number of days with moderate to severe headache lasting more than 4 hours or treated with usual treatments
Timepoint
Before the intervention and 4 and 8 weeks after the intervention
Method of measurement
check list

Secondary outcomes

1

Description
Number of days with migraine
Timepoint
Before the intervention and 4 and 8 weeks after the intervention
Method of measurement
check list

2

Description
Severity of headache on days with headache
Timepoint
Before the intervention and 4 and 8 weeks after the intervention
Method of measurement
MIGSEV scale

3

Description
Doses of analgesics and triptans
Timepoint
Before the intervention and 4 and 8 weeks after the intervention
Method of measurement
check list

Intervention groups

1

Description
Intervention group: L-carnitine 500 mg tablets of Kharazmi Company are crushed and placed inside the capsule and taken once a day orally for one month to be added to the routine migraine prophylaxis treatment.
Category
Prevention

2

Description
Control group: Capsules similar to the intervention group containing 10 mg of starch once a day orally for one month will be added to the routine migraine prophylaxis treatment.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
neurology clinic of Allameh Bohloul Gonabadi Hospital
Full name of responsible person
Negar shafaei bajestani
Street address
Imam Khomeini Street, Gonabad University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Leila Sadegh Moghadam
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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
Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Negar Shafaei Bajestani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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9691797852

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Position

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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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published

To whom data/document is available

The researchers in university and other scientific institutes.

Under which criteria data/document could be used

Applications can be submitted for any project that is useful for the treatment of patients.

From where data/document is obtainable

Data can be accessible through sending an email to the corresponding author. negar.shafaei@mail.com

What processes are involved for a request to access data/document

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments