

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of carnitine supplementation with sodium valproate in the prophylactic treatment of migraine patients.

Protocol summary

Study aim

Comparison of the effect of carnitine supplement with sodium valproate in the prophylactic treatment of patients with migraine

Design

Clinical trial with control group, single blind, randomized, sample size of 80 people

Settings and conduct

All patients who had a definite diagnosis of migraine and had no exit criteria and no other causes associated with headache were single blind and one to the other, so that the first in one group and the other in the other group were divided into two groups

Participants/Inclusion and exclusion criteria

The number of headache attacks is 4 or more in a month 15 to 60 years old No brain degenerative disease. No Pregnancy and lactation they are not alcoholic or drug user They did not have psychiatric disease or chronic liver or kidney disorders No chronic consumption of pain killer They did not use psychedelic drug

Intervention groups

Intervention group L-carnitine and sodium valproate

Main outcome variables

headache severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190702044073N1**

Registration date: **2019-09-01, 1398/06/10**

Registration timing: **retrospective**

Last update: **2019-09-01, 1398/06/10**

Update count: **0**

Registration date

2019-09-01, 1398/06/10

Registrant information

Name

Nazli Barati bagherabad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3162 6000

Email address

nazli.barati@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

2018-12-22, 1397/10/01

Actual recruitment end date

2019-05-22, 1398/03/01

Trial completion date

2019-06-20, 1398/03/30

Scientific title

Comparison of the effect of carnitine supplementation with sodium valproate in the prophylactic treatment of migraine patients.

Public title

Effect of carnitine on migraine prophylaxis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The number of headache attacks is 4 or more in a month 15 to 60 years old No brain degenerative disease. No Pregnancy and lactation they are not alcoholic or drug user They did not have psychiatric disease or chronic liver or kidney disorders No chronic consumption of pain

killer They did not use psychedelic drug

Exclusion criteria:

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method was used individually using random numbers table.

Blinding (investigator's opinion)

Single blinded

Blinding description

All patients who had a definite diagnosis of migraine and had no exit criteria and no other causes associated with headache were single blind and one to the other, so that the first in one group and the other in the other group were divided into two groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Birjand University of Medical Science

Street address

Ghafari Blvd , Birjand university of medical science

City

Birjand

Province

South Khorasan

Postal code

971783577

Approval date

2018-11-12, 1397/08/21

Ethics committee reference number

lr.bums.REC.1397.229

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

headache severity

Timepoint

At the beginning of the study and one month after taking L-Carnitine

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

duration of headache attack

Timepoint

At the beginning of the study and one month after taking L-Carnitine

Method of measurement

hour

2

Description

Frequency of headache repetition

Timepoint

At the beginning of the study and one month after taking L-Carnitine

Method of measurement

Frequency of headache repetition in one month

3

Description

Age

Timepoint

At the beginning of the study

Method of measurement

year old

4

Description

sex

Timepoint

At the beginning of the study

Method of measurement

male , female

Intervention groups

1

Description

Intervention group:

Category

Treatment - Drugs

2

Description

Intervention group:

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital , Neurology Clinic

Full name of responsible person

Fateme Nayab

Street address

Ghafari Blvd , Valiasr Hospital

City

Birjand

Province

South Khorasan

Postal code

9۷۱۷۸۵۳۵۷۷

Phone

+98 56 3244 3000

Fax

+98 56 3244 2088

Email

valiasr@bums.ac.ir

Web page address

<http://valiasr.bums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Deputy of research and technology

Street address

Ghafari Blvd , Birjand university of medical science

City

Birjand

Province

South Khorasan

Postal code

9۷۱۷۸۵۳۵۷۷

Phone

+98 56 3239 5000

Email

public_r@bums.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Nazli Barati

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Ghafari Blvd , Birjand university of medical science

City

Birjand

Province

South Khorasan

Postal code

9۷۱۷۸۵۳۵۷۷

Phone

+98 56 3239 5000

Email

Nazli.barati@bums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Seyed Mohammad Mousavi Mirzaei

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

Street address

Ghafari Blvd , Razi hospital

City

Birjand

Province

South Khorasan

Postal code

9۷۱۷۸۴۴۷۱

Phone

+98 56 3162 6020

Email

razihospital@bums.ac.ir

Web page address

http://razi.bums.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Nazli Barati

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Ghafari Blvd , Birjand university of medical science

City

Birjand

Province

South Khorasan

Postal code

9۷۱۷۸۵۳۵۷۷

Phone

+98 56 3239 5000

Email

nazli.barati@bums.ac.ir

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

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

Title and more details about the data/document

Clinical study report

When the data will become available and for how long

Within 6 months after publishing the results

To whom data/document is available

Scientific and academic researchers

Under which criteria data/document could be used

Use results in other research,

From where data/document is obtainable

Website of Birjand University of Medical Sciences

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

Correspondence with university, approval of deputy research and technology

Comments