Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

۹۷۱۷۸۵۳۵۷۷

Approval date

2018-11-12, 1397/08/21

Ethics committee reference number

Ir.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
۹۷۱۷۸۵۳۵۷۷
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
۹۷۱۷۸۵۳۵۷۷
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
۹۷۱۷۸۵۳۵۷۷
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
۹۷۱۷۸۴۴۴۷۱

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
۹۷۱۷۸۵۳۵۷۷

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