

# 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**

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**Email**

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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**

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**