Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Effect Of Coenzyme 10 (Q10) in Controlling Migraine Headaches in Women 18-45 Years Old

Protocol summary

Study aim
Determining the effect of coenzyme Q10 in controlling migraine headaches

Design
Phase 3 controlled clinical trial with parallel groups on 40 patients

Settings and conduct
This study is being conducted in a psychiatric hospital in Zahedan. At the beginning of the intervention, headache severity will be measured by a questionnaire. In the intervention group, the fixed drug (propranolol 20 to 40 mg plus sodium valproate 200 to 400 mg) along with coenzyme Q10 in the form of 100 mg capsules, one per day for three months. For blinding, the control group will be given a placebo in the same color, dosage, and instructions for taking coenzyme Q10, along with the fixed drug, in addition to routine treatment. Follow-up will be for at least three months.

Participants/Inclusion and exclusion criteria
Entry conditions: Patients with migraine (with or without aura) of both sexes Non-entry conditions: pregnant and lactating women, smokers, alcoholics, history of significant side effects or recent use of melatonin supplements, severe depression within the last year

Intervention groups
In the intervention group, routine medication (propranol with sodium valproate) with coenzyme Q10 will be given one tablet per day for three months. The control group will be given routine medication with placebo with the same dosage instructions as coenzyme Q10. Follow-up will be for at least three months. After the follow-up period, patients will be assessed for headache severity.

Main outcome variables
The severity and frequency of headache attacks; the duration of the headache

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250114064378N1**
Registration date: **2025-02-09, 1403/11/21**
Registration timing: **registered_while_recruiting**

Last update: **2025-02-09, 1403/11/21**
Update count: **0**

Registration date
2025-02-09, 1403/11/21

Registrant information

Name
Behnaz Izadpanahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 54 3352 2637

Email address
b.izadpanahi@zaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-08, 1403/11/20

Expected recruitment end date
2026-02-09, 1404/11/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the Effect Of Coenzyme 10 (Q10) in Controlling Migraine Headaches in Women 18-45 Years Old

Public title
Investigating the Effect Of Coenzyme 10 (Q10) in Controlling Migraine Headaches in Women 18-45 Years Old

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women Aged 18 to 45 Informed Consent to Participate in The Study Completeness of Patient File Information and Records Diagnosis of The Disease By a Doctor Definitive Diagnosis of Migraine

Exclusion criteria:
Suffering from chronic diseases Secondary headache or other types of primary headache except migraine Taking food supplements or medicine Pregnant and lactating women Smokers & alcoholics History of significant side effects or recent use of melatonin supplements Chronic mental illness and a history of severe depression during the last year

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The present study is a double blind randomized parallel clinical trial. The target population includes people with migraines referred to Baharan Hospital in Zahedan, which are diagnosed by a neurologist based on the criteria of the International Headache Association. Random allocation will be done using Block Randomization and blocks of four.And half of the cases are assigned to the intervention group and half of the cases to the control group. All four states are as follows. which in NL A is group one and B is group two. The four states are as follows. which in NL A is group one and B is group two. 1- A A B B 2- A B A B 3- A B B A 4- B B A A 5- B A B A 6- B A A B In the next step, we assign one of the numbers 1 to 6 to each of these four combinations.In the next step, based on the overall sample size and the sample size of the groups, we select about 20 blocks of four randomly and determine their order. Allocation of people to the intervention and control groups will be based on the selected arrangements. By continuing this process, we are sure that the difference between the two groups will not exceed two people at most.

Blinding (investigator's opinion)
Double blinded

Blinding description
If the individual is placed in the intervention group, this group will be given a fixed and routine medication (propranolol 20 to 40 mg with sodium valproate 200 to 400 mg) along with coenzyme Q10 in the form of 100 mg capsules, one per day for three months. For blinding, the control group will be given a placebo in the same color, dosage, and instructions for taking coenzyme Q10, along with the fixed medication, in addition to the routine treatment. Follow-up will be for at least three months and patients will be contacted periodically to ensure medication use. After the follow-up period, patients will be re-evaluated for migraine headache severity. In addition, the two intervention and control groups will be matched in terms of the type of anti-migraine medication used and the dosage of the medication.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences

Street address
Dr.Hesabi Square, Sistan and Baluchestan Province, Zahedan، Integrating the campus of the University of Medical Sciences،

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2024-11-30, 1403/09/10

Ethics committee reference number
IR.ZAUMS.REC.1403.382

Health conditions studied

1

Description of health condition studied
Migraine headache

ICD-10 code
G43.9

ICD-10 code description
Migraine, unspecified

Primary outcomes

1

Description
Severity of headache attacks
Timepoint
day
Method of measurement
Patient statements

2

Description
Frequency of headache attacks
Timepoint
Number
Method of measurement
Patient statements

3

Description
Duration of headache
Timepoint
Clock
Method of measurement
Patient statements

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group is given a fixed and routine medication (propranolol 20 to 40 mg plus sodium valproate 200 to 400 mg) along with coenzyme Q10 in the form of 100 mg capsules, one per day for three months.
Category
Treatment - Drugs

2

Description
Control group: Along with the fixed drug, a placebo will be given in the same color and dosage and instructions for taking Coenzyme 10 drug, along with the routine treatment. Placebo will be prepared in cooperation with Zabul University of Medical Sciences Faculty of Pharmacy.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baharan Psychiatric Hospital
Full name of responsible person
Dr.Behnaz Izadpanahi
Street address
West Imam Khomeini St, Silo Block, Opposite Grain Office, Baharan Psychiatric Hospital, Zahedan Zahedan
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Email
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Web page address
https://irct.behdasht.gov.ir/user/trial/81407/update/recruitment_center

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Dr.Ebrahim Kord
Street address
Dr.Hesabi Square, Sistan and Baluchestan Province, Zahedan، Integrating the campus of the University of Medical Sciences،
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Email
E.kord58@zaums.ac.ir
Web page address
https://irct.behdasht.gov.ir/user/trial/81407/update/sponsor
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Dr. Behnaz Izadpanahi
Position
Psychiatry Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
West Imam Khomeini St, Silo Block, Opposite Grain Office, Baharan Psychiatric Hospital, Zahedan
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https://irct.behdasht.gov.ir/user/trial/81407/update/public_queries_contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Dr. Behnaz Izad panahi
Position
Psychiatry Resident
Latest degree
Medical doctor
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Web page address
https://irct.behdasht.gov.ir/user/trial/81407/update/scientific_queries_contact

Person responsible for updating data

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Behnaz Izad panahi
Position
Psychiatry Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
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West Imam Khomeini St, Silo Block, Opposite Grain Office, Baharan Psychiatric Hospital, Zahedan
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Phone
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Email
b.izadpanahi@zaums.ac.ir
Web page address
https://irct.behdasht.gov.ir/user/trial/81407/update/data_updater_contact

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
Yes - There is a plan to make this available
Title and more details about the data/document
I can share information about the main outcome.
When the data will become available and for how long
"Access period begins 6 months after results are published."
To whom data/document is available
For researchers working in academic and scientific institutions
Under which criteria data/document could be used
Scientific uses

From where data/document is obtainable

To access information, you can email b.izadpanahi@zaums.ac.ir or call 09155683822.

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

A transparent request on the site for access to data by the individual, followed by review of the request by the Vice President for Research within 2 weeks, and then permission to access the data.

Comments