Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Study of the efficacy of CO Q10 in the prophylactic treatment of patient with migraine headache

Protocol summary

Summary

The aim of this study is to evaluate the efficacy of Coenzyme Q10 in the prophylactic treatment of migraine headache. Inclusion criteria are: A definitive diagnosis of migraine based on international headache society criteria and having at least one headache per week or 4 per month. Having another serious disease such as diabetes, hypertension, thyroid disease, or asthma that would interfere with migraine or its preventive treatment are the main exclusion criteria as well as using COQ10 by the patient during the last month before study involvement. This study involves 40 patients with definite diagnosis of migraine headache as the case group who will receive100 mg/ day CoQ10 in addition to their previous prophylactic treatment and 40 control patients with migraine who will continue their traditional anti-migraine treatment. Patients will be visited at 1, 3 and 6 months intervals for evaluation of primary outcomes including severity of the headache, duration of pain attacks, and frequency of headaches as well as presence of associated symptoms such as nausea and vomiting, photophobia and etc.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014083118992N1**
Registration date: **2015-01-29, 1393/11/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-01-29, 1393/11/09

Registrant information

Name

Seyed Mohsen Soltani Sabi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

research grunt by the deputy of research of Mashhad University of Medical Sciences

Expected recruitment start date

2014-09-12, 1393/06/21

Expected recruitment end date

2015-09-12, 1394/06/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the efficacy of CO Q10 in the prophylactic treatment of patient with migraine headache

Public title

Study of the effecacy of CO Q10 in the prophylactic tretment of migraine

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: A definitive diagnosis of migraine based on IHS criteria; having at least one headache per week or 4 per month or having less frequent attacks providing that there is another indication for prophylactic treatment such as suffering from long-lasting disabling

attacks; signing informed consent forms by the patient .Exclusion criteria: Having another serious disease such as diabetes, hypertension, thyroid disease, or asthma that interferes with migraine or its preventive treatment; using COQ10 during the last month before study involvement by the patient for another reason; consuming drugs with potential effects of aggravating migraine attacks such as OCP, nitrate compounds, vasodilatators, ...; failure to follow-up the patient for 6 months.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
00000

Secondary trial Id
00000

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committe of Mashhad University of Medical Sciences

Street address
Qureshi Building, Daneshgah Avenue,Mashhad

City
Mashhad

Postal code
91375-345

Approval date
2013-09-16, 1392/06/25

Ethics committee reference number
920108

Health conditions studied

1

Description of health condition studied
migraine

ICD-10 code
g43

ICD-10 code description
Migraine without aura [common migraine]Migraine with aura [classical migraine]

Primary outcomes

1

Description
headache

Timepoint
1,3,6 months

Method of measurement
Questionnaire

Secondary outcomes

1

Description
Associated symptoms of Migraine

Timepoint
1.3.6 month

Method of measurement
Questionnaires and Interview

Intervention groups

1

Description
control group will receive common treatment for migraine prophylaxis

Category
Treatment - Drugs

2

Description
intervention group will use CoQ10 for six months in addition to their traditional medicines. COQ10 will prescribe with a dose of 100 mg per day orally

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem Hospital

Full name of responsible person

Seyed Mohsen Soltani

Street address

Neurology department, Ghaem Hospital, Ahmadabad street, Mashhad,Khorasan Razavi, Iran

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Department of Mashhad University of Medical Sciences

Full name of responsible person

Saeed Eslami

Street address

Qureshi building, Daneshgah avenue, Mashhad, Iran

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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

Research Department of Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Mohsen Soltani

Position

Neurology resident

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

Ali Shoeibi

Position

Assistant Professor of Neurology

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Position

Neurology Resident

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty