Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The combined effects of nanocurcumin and ubiquinone supplementation on serum levels of homocysteine, calcitonin gene-related peptide, oxidative stress index, gene expression and activity of some antioxidant enzymes in migraine patients: Randomized double blind placebo controlled trial

Protocol summary

Summary

Main objectives of the project: Determination of complementary effects of nanocurcumin and ubiquinone on serum levels of homocysteine, calcitonin gene-related peptide, oxidative stress profile, gene expression, and activity of some antioxidant enzymes in migraine patients. Design Study: Randomized, double-blind, placebo-controlled. The study population: All patients with migraine referring to the Neurology Clinic of Imam Khomeini Hospital in Tehran. Inclusion criteria: 20 to 45 years old; Patients with episodic migraine; Migraine Diagnosis by International Headache Society Criteria as Applied by a Neurologist; No nutritional supplement or professional sports activities four weeks before intervention; People who are willing to cooperate voluntarily. Exclusion criteria: Kidney disease; liver disease; pancreatitis; diabetes; cancer; thyroid disorders and inflammatory diseases based on medical history; Malnutrition (body mass index less than 18.5) and obesity (body mass index greater than 30); Vitamin supplementation during the three months before intervention; Pregnancy; Alcohol consumption over the past six months; smoking; Patients with history of cardiovascular disease; Taking anti-inflammatory drugs or supplements such as ubiquinone and curcumin; Allergic reaction to the ubiquinone and/or Curcumin supplement; Lack of patient collaboration; Any significant changes in diet and routine life. Sample size: 80. Intervention: Patients will be divided into four groups, according to stratified randomization method: 1.The group receiving ubiquinone (sauna medicine in Parseh, Iran) (100 mg three times daily) and nanocorcomin (Sina Kurkamin, Iran) (80 mg per day). 2.Nano-curcumin supplement and ubiquinone placebo (Minoo Co., Iran). 3.ubiquinone Supplement and Curcumin Placebo (Minoo Co., Iran). 4.The control group consisted of patients receiving ubiquinone placebo and curcumin placebo for two months. Primary outcome measure: Number of headache attacks, duration of headache and headache severity. Secondary outcome measure: Laboratory parameters including serum levels of Calcitonin gene-related peptide, homocysteine, oxidative stress profile, catalase, superoxide dismutase, glutathione peroxidase activity and gene expression in PBMC.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080135444N1**
Registration date: **2017-11-06, 1396/08/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-11-06, 1396/08/15

Registrant information

Name

Mohammad Prohan

Name of organization / entity

Tehran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 4223 2693

Email address

prohan-m@razi.tums.ac.ir

Recruitment status
Recruitment complete
Funding source
The costs will be provided by the Vice Chancellor for research, Tehran University of Medical Sciences.

Expected recruitment start date
2017-09-23, 1396/07/01
Expected recruitment end date
2018-03-21, 1397/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The combined effects of nanocurcumin and ubiquinone supplementation on serum levels of homocysteine, calcitonin gene-related peptide, oxidative stress index, gene expression and activity of some antioxidant enzymes in migraine patients: Randomized double blind placebo controlled trial

Public title
The effect of nanocurcumin and ubiquinone in migraine treatment
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: 20 to 45 years old; Patients with episodic migraine; Migraine Diagnosis by International Headache Society Criteria as Applied by a Neurologist; No nutritional supplement or professional sports activities four weeks before intervention; People who are willing to cooperate voluntarily. Exclusion criteria: Kidney disease; liver disease; pancreatitis; diabetes; cancer; thyroid disorders and inflammatory diseases based on medical history; Malnutrition (body mass index less than 18.5) and obesity (body mass index greater than 30); Vitamin supplementation during the three months before intervention; Pregnancy; Alcohol consumption over the past six months; smoking; Patients with history of cardiovascular disease; Taking anti-inflammatory drugs or supplements such as ubiquinone and curcumin; Allergic reaction to the ubiquinone and/or Curcumin supplement; Lack of patient collaboration; Any significant changes in diet and routine life.
Age
From **20 years** old to **45 years** old
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)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
No. 44, Hojjat Doust Alley, Naderi ave, Keshavarz Blvd, Tehran.
City
Tehran
Postal code
Approval date
2017-08-01, 1396/05/10
Ethics committee reference number
IR.TUMS.VCR.REC.1396.3025

Health conditions studied

1

Description of health condition studied
Migraine without aura
ICD-10 code
G43.0
ICD-10 code description
Migraine without aura [common migraine]

Primary outcomes

1

Description
Number of headache attacks
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Questionnaires to assess disease progression

2

Description
Duration of the headache
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Questionnaires to assess disease progression

3

Description
Headache severity
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Questionnaires to assess disease progression

Secondary outcomes

1

Description
Serum level of calcitonin gene-related peptide
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Using appropriate laboratory methods for each variable

2

Description
Serum levels of homocysteine
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Using appropriate laboratory methods for each variable

3

Description
Oxidative stress profile
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Using appropriate laboratory methods for each variable

4

Description
Activity of antioxidant enzymes catalase, superoxide dismutase, glutathione peroxidase
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Using appropriate laboratory methods for each variable

5

Description
Gene expression of anti-oxidant enzymes catalase, superoxide dismutase, glutathione peroxidase in peripheral blood mononuclear cells
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Using appropriate laboratory methods for each variable

Intervention groups

1

Description
Patients will be divided into four groups, according to stratified randomization method: 1.The group receiving ubiquinone (sauna medicine in Parseh, Iran) (100 mg three times daily) and nanocorcomin (Sina Kurkamin, Iran) (80 mg per day). 2.Nano-curcumin supplement and ubiquinone placebo (Minoo Co., Iran). 3.ubiquinone Supplement and Curcumin Placebo (Minoo Co., Iran). 4.The control group consisted of patients receiving ubiquinone placebo and curcumin placebo for two months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology Clinic of Imam Khomeini Hospital in Tehran
Full name of responsible person
Mohammad Prohan
Street address
Neurology Clinic, Imam Khomeini Hospital, End of Keshavarz Blvd, Tehran, Iran.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Mrs. Javadi
Street address
No. 44, Hojjat Doust Alley, Naderi ave, Keshavarz Blvd, Tehran.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Prohan
Position
Ph.D. student
Other areas of specialty/work
Street address
No. 44, Hojjat Doust Alley, Naderi ave, Keshavarz Blvd, Tehran.
City
Tehran
Postal code
Phone
+98 21 8895 5975
Fax
Email
prohan-m@razi.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences and Health Services
Full name of responsible person
Mohammad Prohan
Position
Ph.D. student
Other areas of specialty/work
Street address
No. 44, Hojjat Doust Alley, Naderi ave, Keshavarz Blvd, Tehran.
City
Tehran
Postal code
Phone
+98 21 8895 5975
Fax
Email
prohan-m@razi.tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Prohan
Position
Ph.D. student
Other areas of specialty/work
Street address
No. 44, Hojjat Doust Alley, Naderi ave, Keshavarz Blvd, Tehran.
City
Tehran
Postal code
Phone
+98 21 8895 5975
Fax
Email
prohan-m@razi.tums.ac.ir
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