Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of folic acid and pyridoxine supplementation on symptoms, severity of headache and inflammatory markers in patients with Migraine with aura (MA)

Protocol summary

Summary

The aim of present study is to investigate the effects of pyridoxine and folic acid supplementation on symptoms and inflammatory indices in patients with migraine with aura (MA) for 3 month. Inclusion criteria and exclusion criteria are confirmation of MA by neurologist and the use of pyridoxine and folic acid supplement, respectively. For this purpose, we enroll 120 patients with MA. The participants will categorize to 3 intervention groups and 1 placebo group. Patients in group 1, will receive 80 mg/d pyridoxine and 5 mg/d folic acid. Group 2 and 3 receive 80 mg/d pyridoxine and 5 mg/d folic acid, respectively. Group 4 consider as placebo group. Finally, at first and end of intervention, effect of pyridoxine and folic acid on migraine symptoms (severity , frequency , average duration of migraine attacks) and CRP will investigate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013060411763N9**
Registration date: **2014-04-12, 1393/01/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-04-12, 1393/01/23

Registrant information

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Science, Isfahan, Iran

Expected recruitment start date

2013-02-01, 1391/11/13

Expected recruitment end date

2013-03-01, 1391/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of folic acid and pyridoxine supplementation on symptoms, severity of headache and inflammatory markers in patients with Migraine with aura (MA)

Public title

The effect of folic acid and pyridoxine supplementation on symptoms of migraine

Purpose

Treatment

Inclusion/Exclusion criteria

Patients suffered from migraine in a long time with current diagnosis of MA and a one-year history of severe; recurrent attacks(1 to 8 attacks per month) were selected; The patients with chronic heart disease; previous stroke incidence; chronic renal failure and also with history of taking vitamin B supplements were excluded from the study.

Age
From **15 years** old to **65 years** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **120**
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
Isfahan University of Medical Sciences, Isfahan, Iran
Street address
Isfahan University of Medical Sciences, Isfahan, Iran, Hezargarib street
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Isfahan
Postal code
Approval date
2013-07-24, 1392/05/02
Ethics committee reference number
392363

Health conditions studied

1

Description of health condition studied
Migraine with aura
ICD-10 code
G43.1
ICD-10 code description
Migraine with aura [classical migraine]

Primary outcomes

1

Description
Severity of migraine attacks
Timepoint
First and end of intervention (3 month)
Method of measurement
VAS scale

2

Description
Frequency of migraine attacks
Timepoint
First and end of intervention (3 month)
Method of measurement
Questionnaire

3

Description
Duration of migraine attacks
Timepoint
First and end of intervention (3 month)
Method of measurement
Questionnaire

4

Description
Homocysteine level
Timepoint
First and end of intervention (3 month)
Method of measurement
Laboratory analysis (blood test)

5

Description
Crp level
Timepoint
First and end of intervention (3 month)
Method of measurement
Laboratory analysis (blood test)

Secondary outcomes

empty

Intervention groups

1

Description
Patients in group 3 received 80 mg/d pyridoxine for 12 weeks.
Category
Treatment - Drugs

2

Description
Patients in group 4 considered as control, received placebo (lactose) for 12 weeks.
Category
Placebo

3

Description
patients in group 1 received 5 mg/d folic acid and 80 mg/d pyridoxine for 12 weeks
Category
Treatment - Drugs

4

Description
Patients in group 2 received 5 mg/d folic acid for 12 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khorshid clinic
Full name of responsible person
Dr. Gholamreza Askari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy of Isfahan University of Medical Sciences
Full name of responsible person
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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 Deputy of Isfahan 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

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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