

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

Name

Gholamreza Askari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2110

Email address

askari@mui.ac.ir

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

City

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

Street address

Isfahan, Ostandari street

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Isfahan University of Medical Sciences

Full name of responsible person

Dr Peyman Adibi

Street address

Iran, Isfahan, Hezargarib street, Esfahan university of medical sciences

City

Isfahan

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

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Omid Sadeghi

Position

MSc of Nutrition

Other areas of specialty/work

Street address

Iran, Isfahan, Hezargarib street, Isfahan University of Medical Science

City

Isfahan

Postal code

Phone

+98 31 1792 2658

Fax

Email

omidsadeghi69@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Askari

Position

MD & PhD (Nutritionist)

Other areas of specialty/work

Street address

Iran, Isfahan, Hezargarib street, Isfahan University of Medical Sciences

City

Isfahan

Postal code

Phone

+98 31 1792 2110

Fax

Email

askari@mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Omid Sadeghi

Position

MSc of Nutrition

Other areas of specialty/work

Street address

Isfahan, Hezarjirib street

City

Isfahan

Postal code**Phone**

00

Fax**Email**

omidsadeghi69@yahoo.com

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*