

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of folic acid on migraine headache

Protocol summary

Summary

The Aim of this trial is to study the effect of folic acid on migraine headache. This study is a double-blinded clinical trial. Ninety patients with confirmed migraine headache will randomly allocated into three groups. Migraine headache will be confirmed by the International Headache Society scale (IHS). Intervention 1: conventional therapy (i.e. 10 milligrams Nortriptyline nightly plus 200 milligrams Depakin daily) plus folic acid 1 milligram daily. Intervention 2: conventional therapy (i.e. 10 milligrams Nortriptyline nightly plus 200 milligrams Depakin daily) plus folic acid 5 milligrams daily. control: conventional therapy without folic acid (i.e. 10 milligrams Nortriptyline nightly plus 200 milligrams Depakin daily). We will follow patients monthly after start of treatment to 3 months they will be visited in the neurology clinic again and the intensity and frequency of headache during three months in all groups will be measured by MIDAS scale. Inclusion criteria: 20-50 years; getting no treatment for Migraine in the previous 3 months; not being pregnant or lactating; having no systemic disease or intracranial lesion. Exclusion criteria: any drug side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041920258N39**

Registration date: **2017-06-03, 1396/03/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-03, 1396/03/13

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Arak University of Medical Sciences

Expected recruitment start date

2015-08-25, 1394/06/03

Expected recruitment end date

2016-08-24, 1395/06/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of folic acid on migraine headache

Public title

The effect of folic acid on migraine headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 20-50 years; getting no treatment for Migraine in the previous 3 months; not being pregnant or lactating; having no systemic disease or intracranial lesion. Exclusion criteria: any drug side effects

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 90

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 Arak University of Medical Sciences

Street addressDr Mohammad Rafie, Vice Chancellor Research,
Payambar Azam complex, Basij square, Sardasht,
Arak**City**

Arak

Postal code

38149578558

Approval date

2015-08-24, 1394/06/02

Ethics committee reference number

IR.ARAKMU.REC.1394.155

Health conditions studied**1****Description of health condition studied**

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes**1****Description**

headache

Timepoint

monthly after start of treatment to 3 months

Method of measurement

MIDAS questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**Intervention group 1: 10 milligram nortriptyline nightly
with 200 milligram Depakin daily and folic acid 1
milligram daily.**Category**

Treatment - Drugs

2**Description**Intervention group 2: 10 milligram nortriptyline nightly
with 200 milligram Depakin daily and folic acid 5
milligram daily**Category**

Treatment - Drugs

3**Description**Control group: 10 milligram nortriptyline nightly with 200
milligram Depakin daily.**Category**

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr hospital

Full name of responsible person

Dr Fardin Faraji

Street address

Valiasr hospital, Valiasr square, Arak

City

Arak

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice Chancellor For Research, Arak University of
Medical Sciences**Full name of responsible person**

Dr Mohammad Rafiee

Street addressVice Chancellor For Research, Payambar Azam
Complex, Basij square, Sardasht, Arak**City**

Arak

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, Arak 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

Valiasr hospital

Full name of responsible person

Dr Maleki rad

Position

Neuropsychologist

Other areas of specialty/work

Street address

Valiasr Hospital, Arak

City

Arak

Postal code

3814957558

Phone

+98 863222003

Fax

+98 86 3471 3638

Email

Malekirad@arakmu.ac.ir

Web page address

-

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Fardin Faraji

Position

Faculty member, Neurologist

Other areas of specialty/work

Street address

Valiasr hospital, Valiasr square, Shahid Shirodi street, Arak

City

Arak

Postal code

3814957558

Phone

+98 863222003

Fax

+98 86 3417 3638

Email

faraji@yahoo.com

Web page address

-

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alaleh Amirak

Position

Medical student

Other areas of specialty/work

Street address

Payambarazam Complex, Basij Square, Sardasht, Arak

City

Arak

Postal code

3814957558

Phone

+98 863222003

Fax

+98 86 3417 3638

Email

alalehamirak@gmail.com

Web page address

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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