

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of Iron therapy on severity and frequency of migraine headaches of 15-45 year old patients with iron deficiency

Protocol summary

Summary

Objectives: This study is carried out to evaluate the effect of iron therapy on severity and duration of headache attacks in migraineous with iron deficiency.

Designed: In this semi-experimental study, 90 women aged 15-45 year with migraine in Shahrekords Ayatallah Kashany clinic, will be assigned, into three groups (N=30 each) include, A: with negative balance of iron, B: with iron deficiency anemia, C: with normal level of iron.

Interventions: All 3 groups will be prescribed 400mg valproate Na daily for 45 days, the second period of the study all patients will be received extra iron sulfate (3 tablets). It is allowed to give the patients 25mg Indometasine capsule if it is necessary. Data collection: Patients will be followed up every 15 days by either direct visit or phone. At the end of each period, in addition to collecting related Smear questionnaire, the samples of peripheral blood and iron supply will be collected. Exclusion criteria: Pregnancy, breast feeding, using psychiatric drugs, oral contraceptive pill or other sexual hormones, having systemic disease such as hypertension and asthma. Main outcome measures: Frequency and severity of headache attacks will be recorded and compared in three groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107117004N1**
Registration date: **2011-10-29, 1390/08/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-10-29, 1390/08/07

Registrant information

Name

Shamsali Khosravi

Name of organization / entity

Shahrekord Medical University

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahrekord University of Medical Sciences

Expected recruitment start date

2011-08-10, 1390/05/19

Expected recruitment end date

2012-02-27, 1390/12/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Iron therapy on severity and frequency of migraine headaches of 15-45 year old patients with iron deficiency

Public title

Iron therapy in migraine headache

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Female Patients having migraine; age between 15 to 45 years; the first group with negative balance of iron; the second group with iron deficiency;

third group with normal level of iron. (Patients with the following characters will be considered as iron deficiency (MCHC<30g/d,MCV<80fl,Tibc>360µg/dl, MCH<27pg/d,Hb<10g/dl, HCT). Patients with ferritin less than 20 microgram in liter will be considered as negative balance of iron.) Exclusion criteria: Pregnancy, lactation, using psychiatric, OTC or other sexual hormones, having systemic illness such as hypertension, asthma.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Shahrekord University of Medical Sciences

Street address

Kashani Street

City

Shahrekord

Postal code

8136893669

Approval date

2008-03-05, 1386/12/15

Ethics committee reference number

5-12-86

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

frequency of headache attacks

Timepoint

three periods of 15 days

Method of measurement

questionnaire

2

Description

severity of headache attacks

Timepoint

three periods of 15 days

Method of measurement

questionnaire

Secondary outcomes

1

Description

Ferritin

Timepoint

At the beginning and at the end of the study

Method of measurement

Laboratory methods

2

Description

blood iron

Timepoint

At the beginning and at the end of the study

Method of measurement

laboratory methods

Intervention groups

1

Description

in negative balance of iron group will receive 400 mg/day valproate Na in all periods (45 days each period) and iron sulfate (50mg/day) in second period of the study.

Category

Treatment - Drugs

2

Description

in iron deficiency anemia group will receive 400 mg/day valproate Na in all periods (45 days each period) and iron sulfate (50mg/day) in second period of the study.

Category

Treatment - Drugs

3

Description

in normal level of iron group will receive 400 mg/day valproate Na in all periods (45 days each period) and iron sulfate (50mg/day) in second period of the study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariaty street , Ayatollah Kashani Hospital

Full name of responsible person

Mahmoud Mirzaei M.D

Street address

10 Shariaty street, Shahrekord, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahrekord University of Medical Sciences

Full name of responsible person

Mahmoud Mobasheri

Street address

Vice chancellor for research, Shahrekord University of Medical Sciences, Kashani Bld

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Shahrekord

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, Shahrekord 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

SHahrekord University of Medical Sciences

Full name of responsible person

Mahmoud Rafeian

Position

Head of Medical Plants Research Center, professor of pharmacology

Other areas of specialty/work

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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