Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 , tha second period of the study all patients will be recieved exrera 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 additon 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 con teraceptive pill or other sexual hormons , having systemic disease such as haypertnsion and asthma . Main outcome mesures: 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

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