

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 1333 4754

##### Email address

khosravishamsali@skums.ac.ir

#### 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

###### City

SHahrekord

### 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

###### City

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

##### Street address

10 Rahmatieh, Medical Plants Research Center, Shahrekord, Iran

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### Person responsible for scientific 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*