# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Clinical trial to comparison the effect of omega-3 supplements and placebo on pediatric migraine prophylaxis in children treated with valproate sodium

## Protocol summary

**Summary**

Migraine is the most frequent type of headache in children and preventive therapy is an important part of its management. It has been shown that administration of omega-3 fatty acids maybe reduces migraine headache attack frequency but because of different and not enough information especially in children, we decide to do this study. The purpose of this study is to show efficacy and safety of omega-3 fatty acid supplements in prophylaxis of migraine headache in children. In this randomized double blind clinical trial study, at least twenty four 5-14 year old children with migraine headache whom were referred to Pediatric Neurology Clinic of Besat Hospital and Imam Khomeini Clinic in Hamedan are distributed into two groups. In one group (case) tablet or syrup of valproate sodium with one omega-3 capsule contain of 1 gr fish oil will be prescribed and in other one (control) tablet or syrup of valproate sodium with one placebo capsule (without any active ingredient) will be given. Number, severity and disability grade of migraine headache and clinical general impression are to be compared before and after three months of treatment.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2013092914809N1**
Registration date: **2013-11-30, 1392/09/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2013-11-30, 1392/09/09

**Registrant information**

**Name**
Mahsha Sangestani
**Name of organization / entity**
Hamedan University of Medical Science
**Country**
Iran (Islamic Republic of)
**Phone**
+98 81 1838 0574
**Email address**
m.sangestani@ymail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

Hamedan University of Medical Science

**Expected recruitment start date**

2013-08-23, 1392/06/01

**Expected recruitment end date**

2014-02-20, 1392/12/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Clinical trial to comparison the effect of omega-3 supplements and placebo on pediatric migraine prophylaxis in children treated with valproate sodium

**Public title**

Effects of omega-3 supplements on prophylaxis of pediatric migraine

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: 1.children in 5-14 years old age

2.Having migraine headache based on International Headache Society Criteria 3.Having frequent or disabling headaches that prophylactic therapy indicated in them (one or more headache attack per week or, three or more headache attacks per month or, more than one school day lost per month) Exclusion Criteria: 1.Diagnosis changes each time during the study 2.Secondary headaches or other neurologic disorders 3.Not to use drugs correctly

**Age**

From **5 years** old to **14 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

Placebo capsules with the same color, package, and shape as omega-3 capsules are produced by Zahravi Pharmaceutical Company. Patients are considered in one of two groups, A or B, with simple random sampling method and the code will be assigned to each of them. The patient and physician are unaware of the contents of the medical groups. The patients will be treated by the physician and they will be followed for at least 3 months. The frequency and severity of headache will be registered. At the end of treatment and after the registration of patient information, codes will be unveiled.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Hamedan University of Medical Science

**Street address**

School of Medicine, Shahid Fahmide Blvd. Pazhuhesh Crossroad

**City**

Hamedan

**Postal code**

**Approval date**

2013-09-10, 1392/06/19

**Ethics committee reference number**

16/35/9/1693/د/پ

## Health conditions studied

### 1

**Description of health condition studied**

migraine

**ICD-10 code**

G43

**ICD-10 code description**

migraine

## Primary outcomes

### 1

**Description**

Monthly frequency of headache

**Timepoint**

Before and after three months of treatment

**Method of measurement**

Asking from patient

### 2

**Description**

Severity of headache

**Timepoint**

Before and after three months of treatment

**Method of measurement**

Asking from patient

### 3

**Description**

Pediatric Migraine Disability Grade (pedMIDAS)

**Timepoint**

Before and after three months of treatment

**Method of measurement**

Asking from patient

### 4

**Description**

Clinical general impression

**Timepoint**

Before and after three months of treatment

**Method of measurement**

Asking from patient

## Secondary outcomes

### 1

**Description**

Omega-3 side effects including gastrointestinal side effects and allergy

**Timepoint**

Monthly until three months of treatment

**Method of measurement**
Clinical exam and asking from patients

## Intervention groups

### 1

**Description**
Twenty mg/kg/day valproate sodium daily in 2 divided doses with one omega-3 capsule contain of 1 gr fish oil, Produced by Zahravi Pharmaceutical Company, for 3 months (intervention)
**Category**
Treatment - Drugs

### 2

**Description**
Twenty mg/kg/day valproate sodium daily in 2 divided doses with one placebo capsule (as the same color, package, and shape as omega-3 capsule without any active ingredient, Produced by Zahravi Pharmaceutical Company) for 3 months (control)
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Imam Khomeini Clinic
**Full name of responsible person**
Afshin Fayyazi
**Street address**
Imam Khomeini Clinic, Mirzade Eshghi St.
**City**
Hamedan

### 2

**Recruitment center**
**Name of recruitment center**
Pediatric Neurology Clinic of Besat Hospital
**Full name of responsible person**
Afshin Fayyazi
**Street address**
Besat Hospital, Shahid Motahari Blvd. Resalat Sq.
**City**
Hamedan

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Vice Chancellor for Research and Technology, Hamedan University of Medical Science
**Full name of responsible person**
Saeed Bashiriyan
**Street address**
Vice Chancellor for Research and Technology, Hamedan University of Medical Science, Shahid Fahmide Blvd. Pazhuhesh Crossroad
**City**
Hamedan
**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 and Technology, Hamedan University of Medical Science
**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**
Hamedan University of Medical Science, School of Medicine
**Full name of responsible person**
Afshin Fayyazi
**Position**
Pediatric Neurologist/Assistant Professor
**Other areas of specialty/work**
**Street address**
Pediatric Department, Besat Hospital, Shahid Motahari Blvd. Resalat Sq.
**City**
Hamedan
**Postal code**
**Phone**
+98 811264002030
**Fax**
**Email**
afshin.fayyazi@yahoo.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Hamedan University of Medical Science, School of Medicine
**Full name of responsible person**
Afshin Fayyazi
**Position**
Pediatric Neurologist, Assistant professor
**Other areas of specialty/work**

**Street address**
Pediatric Department, Besat Hospital, Shahid Motahari Blvd. Resalat Sq.
**City**
Hamedan
**Postal code**
**Phone**
+98 811264002030
**Fax**
**Email**
afshin.fayyazi@yahoo.com
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Hamedan University of Medical Science
**Full name of responsible person**
Mahsha Sangestani
**Position**
Medical Student/ Intern
**Other areas of specialty/work**
**Street address**
Hamedan University of Medical Science, Shahid Fahmide Blvd. Pazhuhesh Crossroad
**City**
Hamedan
**Postal code**
**Phone**
00
**Fax**
**Email**
M.Sangestani@ymail.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*