

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of single dose sodium valproate (Depakine) versus Dexamethasone Intravenously for treatment of acute migraine headache

Protocol summary

Summary

Migraine is a chronic neurologic disorder that it defined by frequent headache, nausea, photophobia and phonophobia for duration 4-72. Sodium valproate has been shown to have both central and peripheral that may have relevance in its ant migraine effects. In the most of studies high dose dexamethasone and valproate are used for treatment of migraine. In this study we will use low dose drugs. Ninety patients, aged 15 to 65 years, presenting with typical migraine according to IHS criteria that admit at Boali hospital were enrolled. This study is prospective randomized double blind clinical trials. Participants are in two group A and B. a group get amp. Dexamethasone 8 mg and another group get Depakine 400 mg intravenous slowly. For assessing severity of headache used from grading scale. Pain, photophobia, phonophobia and vomiting recorded at 0.5,1, 3, 6, 24 hours after injection. Inclusion criteria: age (15-65); acute migraine headache according to criteria HIS; duration: lower than 48 hours; a history of migraine headache from 6 month ago; not consumption NSAID from 24 hours ago and valproate Na as prophylaxis from 2 weeks ago. Exclusion criteria: pregnancy; breastfeeding; fever; allergy to drug. Peptic ulcer; GIB from 1 year ago; diabetes and liver disorder and urea cycle defect.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014022116666N1**
Registration date: **2014-06-22, 1393/04/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-22, 1393/04/01

Registrant information

Name

Narges Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3311 6275

Email address

n.karimi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Scinces

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of single dose sodium valproate (Depakine) versus Dexamethasone Intravenously for treatment of acute migraine headache

Public title

Comparison of single dose sodium valproate versus Dexamethasone Intravenously for treatment of acute migraine headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 15-65 years old; acute

migraine headache according to criteria IHS; duration lower than 48 hours; history of migraine headache from 6 month ago; no consumption NSAID from 24 hours ago and valproate Na as prophylaxis from 2 weeks ago. Exclusion criteria: pregnancy; breastfeeding; fever; allergy to drugs; peptic ulcer, GIB from 1 year ago; diabetes melitus and liver disorder and urea cycle defect.

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

N/A

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

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Jooybar three way, Valiasr blv.

City

Sari

Postal code

Approval date

2014-03-05, 1392/12/14

Ethics committee reference number

565

Health conditions studied

1

Description of health condition studied

Migraine headache

ICD-10 code

G43.9

ICD-10 code description

Migraine, unspecified

Primary outcomes

1

Description

Headache severity

Timepoint

30 minutes, 1, 3, 6 and 24 hours after intervention

Method of measurement

Grading 1-4 and qualitative

Secondary outcomes

1

Description

Photophobia

Timepoint

1, 3, 6, 24 and 72 hours after intervention

Method of measurement

Questionnaire

2

Description

Vomiting

Timepoint

1, 3, 6, 24 and 72 hours after intervention

Method of measurement

Questionnaire

3

Description

phonophobia

Timepoint

1,3,6,24,72 hours

Method of measurement

questionnaire

Intervention groups

1

Description

Control group: amp dexamethasone 8 mg intravenously

Category

Treatment - Drugs

2

Description

Intervention: valproate Na(depakine) 400 mg intravenously

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali Sina hospital

Full name of responsible person

Narges Karimi

Street address

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ahmadali Enayati

Street address

Deputy research and information technology,
Mazandaran University of Medical Sciences

City

Sari

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Narges Karimi

Position

Neurologist, assistant professor

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