Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 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 Booali 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 Sicences

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 dexamethasome 8 mg interavenously

Category
Treatment - Drugs

2

Description
Intervention: valproat 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
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Position
Neurologist, assistant professor
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Person responsible for updating data

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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