Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of intravenous sodium valproate versus dexamethasone on headache relief in patients with acute migraine headache: a double blinded randomized clinical trial

Protocol summary

Summary

Objectives: To investigate the effect of intravenous sodium valproate versus dexamethasone on acute migraine headache Design: Double blinded randomized controlled trial Setting and conduct: Patients who will refer to emergency ward of Beasat and Farshchian hospitals during study period Participants including major eligibility criteria: age of 18 to 65 years; history of having migraine for at least one year; severity of headache equal to or greater than 5 VAS Intervention: A single dose of 400 mg sodium valproate plus 50 mL saline normal solution within 15 min intravenously, versus a single dose of 16 mg dexamethasone plus 50 mL saline normal solution within 15 min intravenously Main outcome measures: Severity of headache using VAS scale will be measured at baseline, one half and two hours later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202199014N1**
Registration date: **2012-03-24, 1391/01/05**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-03-24, 1391/01/05

Registrant information

Name

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Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vic-chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2012-04-21, 1391/02/02

Expected recruitment end date

2012-10-23, 1391/08/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intravenous sodium valproate versus dexamethasone on headache relief in patients with acute migraine headache: a double blinded randomized clinical trial

Public title

The effect of intravenous sodium valproate versus dexamethasone on acute migraine headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 65 years; history of having migraine for at least one year; severity of headache equal to or greater than 5 VAS

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **72**

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

Local Human Subject Review board of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shaheed Fahmideh Ave.

City

Hamadan

Postal code

6517838695

Approval date

2012-02-27, 1390/12/08

Ethics committee reference number

D/P/16/35/9/4452

Health conditions studied

1

Description of health condition studied

Acute migraine headache

ICD-10 code

G43

ICD-10 code description

Migraine with or without aura

Primary outcomes

1

Description

Severity of headache

Timepoint

At baseline and then 0.5 hour and 2 hours later

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

1

Description

Any side effect such as allergy

Timepoint

0.5 hour and 2 hours later

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention 1: A single dose of 400 mg sodium valproate plus 50 mL saline normal solution within 15 min intravenously.

Category

Treatment - Drugs

2

Description

Intervention 2: A single dose of 16 mg dexamethasone plus 50 mL saline normal solution within 15 min intravenously.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Beasat and Farshchian Hospitals

Full name of responsible person

Shahir Mazaheri

Street address

Farshchian Hospital, Mirzadeh Eshghi Ave.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vic-Chancellor of Research and Technology, Hamadan University of Medical Sciences

Full name of responsible person

Ahmad Tavilani

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Hamadan University of Medical Sciences, Shaheed Fahmideh Ave
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Grant name
از محل يك درصد بودجه طرح‌هاي تحقيقاتي دانشگاه
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vic-Chancellor of Research and Technology, Hamadan 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
Research Center for Health Sciences, Department of Epidemiology & Biostatistics
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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