

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

clinical trial of comparison between intravenous sodium valproate and subcutaneous sumatriptan with intramuscular metoclopramide for treatment of acute attacks in patients with migraine headaches

Protocol summary

Summary

Triptans and Ergot compounds are currently used as first line agents for treatment of moderate to severe migraine headaches, but each of these drugs have their own limitations and complications. Intravenous Sodium Valproate also is a relatively safe , effective and rapidly acting drug for treatment of migraine attacks according to recent preliminary studies. In this open-label single-centre randomized prospective phase-2 clinical trial, a total of 60 moderate to severe migraine attacks in patients with an established diagnosis of migraine without aura who seek medical care within 72 hours of symptoms onset were administered either single dose 400 mg intravenous valproate diluted in 100 cc Normal Saline or 10 mg intramuscular metoclopramide followed 10 minutes later by 6 mg subcutaneous Sumatriptan. Exclusion criteria include occurrence serious adverse effects any time during drug administration. Headache severity will be assessed by visual analog scale before treatment, and after 2, 4, and 24 hours of treatment. Potential complications also will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104096154N1**
Registration date: **2011-06-07, 1390/03/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-06-07, 1390/03/17

Registrant information

Name

Babak Bakhshayesh

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Guilan university of medical science,Vice chancellor for research

Expected recruitment start date

2011-04-21, 1390/02/01

Expected recruitment end date

2011-07-23, 1390/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

clinical trial of comparison between intravenous sodium valproate and subcutaneous sumatriptan with intramuscular metoclopramide for treatment of acute attacks in patients with migraine headaches

Public title

comparison of intravenous sodium valproate versus subcutaneous sumatriptan and intramuscular metoclopramide for treatment of acute migraine attacks

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria include :fulfilling international headache society criteria for migraine without aura; absence of cardiovascular disease; absence of cerebrovascular disease; absence of drug allergy; absence of pregnancy; age between 16 to70 year-old. Exclusion criteria include :occurrence of serious adverse drug effects at any time during drug administration.

Age

From **16 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

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

Ethics committee of Guilan university of medical sciene

Street address

across Alzahra hospital, Namjoo street, Siadati street

-

City

Rasht

Postal code

4144665385

Approval date

2011-01-29, 1389/11/09

Ethics committee reference number

12414

Health conditions studied

1

Description of health condition studied

migraine without aura

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura [common migraine]

Primary outcomes

1

Description

headache severity

Timepoint

before treatment,after 2, 4 , and 24 hours

Method of measurement

visual analog scale

Secondary outcomes

1

Description

side effects profile

Timepoint

before treatment ,after 2 , 4, and 24 hours

Method of measurement

history taking and physical examination

Intervention groups

1

Description

Single dose 10 mg intramuscular Metoclopramide injection followed 10 minutes later by single dose 6 mg subcutaneous Sumatriptan injection

Category

Treatment - Drugs

2

Description

Sodium Valproate 400 mg single dose diluted in 100 cc Normal Saline infusion over 10 minutes

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Poorsina hospital of Rasht

Full name of responsible person

Dr Hamidreza Hatamian

Street address

Poorsina hospital of Rasht - Neurology department

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Science, Vice chancellor for research

Full name of responsible person

Dr Abdolrasool Sobhani

Street address

Across Alzahra hospital, Siadati street, Namjoo street

-

City

Rasht

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Guilan University of Medical Science, Vice chancellor for research

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**

Poorsina hospital of Rasht, Guilan University of Medical Sciences

Full name of responsible person

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Position

Neurologist, Associate professor

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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