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 1oo 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

+98 13 1776 1031

Email address

bakhshayesh@gums.ac.ir

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 hospitalt, 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
Dr Hamidreza Hatamian

Position
Neurologist, Associate professor

Other areas of specialty/work

Street address
Guilan University of Medical Sciences, Across Azodi stadium, Namjoo street

City
Rasht

Postal code

Phone
+98 13 1322 2444

Fax

Email
babak.bakh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Poorsina hospital, Guilan Uuniversity of Medical Science

Full name of responsible person
Dr Babak Bakhshayesh Eghbali

Position
Assistant professor, Neurologist

Other areas of specialty/work

Street address
Poorsina Hospital

City
Rasht

Postal code

Phone
+98 13 1322 2444

Fax

Email
bakhshayesh@gums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Poorsina hospital, Guilan university of medical science

Full name of responsible person
Dr Babak Bakhshayesh Eghbali

Position
Neurologist, Assistant professor

Other areas of specialty/work

Street address
Poorsina hospital

City
Rasht

Postal code

Phone
+98 13 1322 2444

Fax

Email
bakhshayesh@gums.ac.ir

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