Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

A Comparision of Granisetron and Metoclopramide in the treatment of nausea and vomiting in patients with migraine headache

Protocol summary

Summary

This is a double blinded randomized trial performed on patients with migraine headache presenting to Sina and Rasool Akram emergency departments. The samples were selected from patients with known migraine headaches who fulfilled the inclusion criteria. Patients without previous history of migraine headache or those in whom the diagnosis was not certain were excluded. Granicetrone was used 2 mg intravenously and it's effects was compared with that of 10 mg intravenous metoclopramide. These drugs were stored in syranges with A and B tags and the patients randomly recieved one of the two drugs based on random block design. Only the chief investigator knows which patient recieved which drug and the rest of investigators were blinded. Pateints were divided into two groups: A, B. Group A recieved 2 mg granicetrone and group B 10 mg metoclopramide. Pain intensity and vomiting episodes were recorded before and 1, 2, 4 hours after drug administration in questionnairs. Patients were examined carefully by investigator and any adverse effect was recorded. Accuracy of this study is 5% with 95% confidence interval and sample size is 150. P value less than 0.05 is considered statistically significant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112038292N1**
Registration date: **2013-01-31, 1391/11/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-01-31, 1391/11/12

Registrant information

Name
Hasan Amiri
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 2235 5477
Email address
h-amiri@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-09-20, 1391/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparision of Granisetron and Metoclopramide in the treatment of nausea and vomiting in patients with migraine headache

Public title

A Comparison of Granisetron and Metoclopramide in the treatment of nausea and vomiting in patients with migraine headache

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Patients older than 18 presenting with migraine headache to sina and rasool akram emergency;

Have a previous history of migraine headache which was diagnosed by a neurologist; Not being pregnant; No breast feeding; No history of psychiatric disorder in the patient or first degree relatives exclusion criteria: Patient's incoopration; Headache's charectristics is different from previus attacks; Sudden oncet headache; Abnormal neurologic exam; uncertainity in diagnosis; Head trauma in the previous month

Age
From **18 years** old to **100 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **150**

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
Ethics Committee of Tehran University of Medical Sciences

Street address
Ghods building, Ghods and Keshavars crossroad

City
Tehran

Postal code

Approval date
2012-10-11, 1391/07/20

Ethics committee reference number
1601/130/91/د

Health conditions studied

1

Description of health condition studied
migraine headache

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
Number of nausea and vomiting episodes

Timepoint
Before, 1, 2, 4 hours after intervention

Method of measurement
Standard Questionnaire

Secondary outcomes

1

Description
Headache intensity

Timepoint
Before, 1, 2, 4 hours after intervention

Method of measurement
Verbal numerical rating scale

2

Description
Adverse effects

Timepoint
Before, 1, 2, 4 hours after intervention

Method of measurement
Standard Questionnaire

Intervention groups

1

Description
In case group the patients received 2 mg granicetrone single dose intravenously

Category
Treatment - Drugs

2

Description
In control group the patients received 10 mg metoclopramide single dose intravenously

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina hospital

Full name of responsible person
Dr. Mehrnaz Nikuyeh MD

Street address

Imam Khomeini avenue

City

Tehran

2

Recruitment center

Name of recruitment center

Rasool Akram hospital

Full name of responsible person

Dr. Mehrnaz Nikuyeh MD

Street address

Niayesh Street, Satarkhan Avenue

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotuhi

Street address

Tehran University of Medical Science, Enghelab Avenue

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran university of medical sciences

Full name of responsible person

Dr. Hasan amiri MD

Position

Associated professor

Other areas of specialty/work

Street address

Imam Khomeini avenue, Sina hospital

City

Tehran

Postal code

Phone

+98 21 63120

Fax

Email

h_amiri@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran university of medical science

Full name of responsible person

Dr. Hasan amiri MD

Position

Associated professor

Other areas of specialty/work

Street address

Imam Khomeini avenue, Sina hospital

City

Tehran

Postal code

Phone

+98 21 63120

Fax

Email

h_amiri@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran university of medical sciences

Full name of responsible person

Dr. Mehrnaz Nikuyeh

Position

Emergency medicine resident

Other areas of specialty/work

Street address

2, 5th Sarvestan street, Hakimieh

City

Tehran

Postal code

9183644473

Phone

+98 21 7730 1718

Fax

Email

shirin01358@gmail.com

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