

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 syringes 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 questionnaires. 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

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Name of organization / entity

Tehran University of Medical Sciences

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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 incooperation; Headache's characteristics is different from previous attacks; Sudden onset headache; Abnormal neurologic exam; uncertainty 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

1601/130/91/3

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 granisetron 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
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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