Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Effect of Ondansetron and Metoclopramide in Treatment of Nausea and Vomiting in Head Trauma Patients

Protocol summary

Summary

Introduction: This study aims to compare the effect of Ondansetron and Metoclopramide on nausea/vomiting in patients with head trauma referred to Imam Hossein Hospital. Design: Randomized, double-blind controlled trial. Method: The total number of 130 patients are involved who are randomly divided into two groups of 65. They recieve Metoclopramide, 10 mg or Ondansetron, 4 mg. Nausea/vomiting in patients is evaluated by a VAS (Visual Analogue Scale) self score after 20 minutes. Need for repeated dose of drug and any adverse event is also recorded. Inclusion criteria: Patients with head trauma and nausea or vomiting who require anti emetic injection with GCS >=13; age over 15; without metabolic and gastrointestinal disease. Exclusion criteria: Hemodynamic instability; Pregnancy, Breast feeding, Alcohol use; Chemotherapy or radiation therapy; Prior use of antiemetics within 8 hours; Opioid use; Prior intravenous fluid administration; Vertigo; Allergy to study drugs; Neurologic deficit. Main outcome measure: Nausea or vomiting.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010231731N1**
Registration date: **2017-01-21, 1395/11/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-21, 1395/11/02

Registrant information

Name

Hosein Partovinejad

Name of organization / entity

Imam Hossein Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 73430

Email address

biglari-m@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-09-01, 1395/06/11

Expected recruitment end date

2017-02-01, 1395/11/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Ondansetron and Metoclopramide in Treatment of Nausea and Vomiting in Head Trauma Patients

Public title

Treatment of Nausea and Vomiting in Head Trauma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: History of head trauma; Presence of nausea or vomiting; Triage level of 3 or more; GCS >=13, age over 15. Exclusion criteria: Unstable hemodynamics; Pregnancy or breast feeding; Neurologic deficit; Restless leg syndrome; Alcoholism; Prior use of antiemetics within 8 hours; Opioid use; Prior intravenous

fluid administration; Vertigo; Chemotherapy; Radiotherapy; History of allergy or adverse reaction to metoclopramide or ondansetron; inability to complete trial or record outcomes.

Age
From **15 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **130**

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 Shahid Beheshti University of Medical Sciences

Street address
Faculty of medicine, Shahid Beheshti University of Medical Sciences, Evin

City
Tehran

Postal code
1985717434

Approval date
2016-02-16, 1394/11/27

Ethics committee reference number
IR.SBMU.SM.REC.1394.209

Health conditions studied

1

Description of health condition studied
Head Trauma

ICD-10 code
S00

ICD-10 code description
Superficial injury of head

Primary outcomes

1

Description
Nausea / Vomiting

Timepoint
Before and 20 minutes after injection

Method of measurement
VAS score (visual analog scale)

Secondary outcomes

1

Description
Drug adverse effect including extrapyramidal effects, dyskinesia

Timepoint
at discharge

Method of measurement
clinical exam

2

Description
Need for repeating injection

Timepoint
20 minutes after first injection

Method of measurement
VAS score (Visual Analog Scale)

Intervention groups

1

Description
Intervention group 1: Intravenous Metoclopramide, 10 mg/2ml once injection

Category
Treatment - Drugs

2

Description
Intervention group 2: Intravenous Ondansetron, 4mg/2ml, Once injection

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hossein Hospital

Full name of responsible person
Hosein Partovinejad

Street address
Madani st., Nezam Abad

City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Ali Ziaei
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3rd floor, Faculty of medicine, Shahid Beheshti University of Medical Sciences, Evin
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Grant name
Grant code / Reference number
113
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Shahid Beheshti 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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Person responsible for updating data

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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