

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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 receive 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

Hossein 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

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

Street address

3rd floor, Faculty of medicine, Shahid Beheshti University of Medical Sciences, Evin

City

Tehran

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hosein Partovinejad

Position

Resident of emergency medicine

Other areas of specialty/work

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biglari-m@razi.tums.ac.ir

Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Biglari

Position

Attending physician internal medicine

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hosein Partovinejad

Position

Resident of emergency medicine

Other areas of specialty/work

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Fax

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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