

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison the antiemetic effect of metoclopramide and ondansetron in patients with minor head trauma

Protocol summary

2018-04-15, 1397/01/26

Study aim

Comparison the antiemetic effect of metoclopramide and ondansetron in patients with minor head trauma referred to Shahid Hasheminezhad Hospital

Design

In this randomized controlled clinical trial 180 patients with minor head trauma will be divided in to three groups with sealed envelope.

Settings and conduct

This this randomized controlled clinical trial will be conducted in eme reza hospital emergency department. Participant, Outcome assessor, Data analyser will be unaware of intervention.

Participants/Inclusion and exclusion criteria

inclusion criteria are patients with minor head trauma suffer from nausea and vomiting with normal brain CT scan, GCS=15 and head trauma in the first 24 hours will be enrolled the study. patients will be excluded from study whom have multiple trauma, chronic disease, hypersensitivity to metoclopramide and ondansetron.

Intervention groups

10 mg metoclopramide 4 mg ondansetron 4 ml normal saline

Main outcome variables

nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170609034403N3**

Registration date: **2018-04-15, 1397/01/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-15, 1397/01/26**

Update count: **0**

Registration date

Registrant information

Name

Hamideh Feiz Disfani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 5312

Email address

feyzh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mashhad University of Medical Sciences

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-07-21, 1397/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the antiemetic effect of metoclopramide and ondansetron in patients with minor head trauma

Public title

Comparison the antiemetic effect of metoclopramide and ondansetron in patients with minor head trauma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

minor head trauma with nausea and vomiting normal brain CT scan GCS=15 head trauma in the first 24 hours

Exclusion criteria:

multiple trauma chronic disease hypersensitivity to metoclopramide and ondansetron

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

information about intervention groups will be saved in sealed envelopes and researcher will select one envelope for each patient accidentally.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participant, Outcome assessor physician, Data analysts will be unaware of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ghoreyshi Building, Daneshgah Streets, Mashhad

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Province

Razavi Khorasan

Postal code

1234568

Approval date

2017-04-19, 1396/01/30

Ethics committee reference number

IR.MUMS.fm.REC.1395.642

Health conditions studied

1

Description of health condition studied

Minor head trauma

ICD-10 code

S06.0

ICD-10 code description

Comotio cerebri

Primary outcomes

1

Description

decrease in nausea and vomiting

Timepoint

before drug administration, 15 and 30 minutes after drug administration

Method of measurement

Qualitative

Secondary outcomes

1

Description

Satisfaction of treatment

Timepoint

15 and 30 minutes after drug administration

Method of measurement

Qualitative

2

Description

Adverse effects

Timepoint

15 and 30 minutes after drug administration

Method of measurement

Qualitative

3

Description

Need for rescue medication

Timepoint

15 and 30 minutes after drug administration

Method of measurement

Qualitative

Intervention groups

1

Description

Intervention group: 4 mg ondansetron

Category

Treatment - Drugs

2

Description

Intervention group: 10 mg metoclopramide

Category

Treatment - Drugs

3

Description

Control group: without drug

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Hasheminezhad Hospital

Full name of responsible person

Hamideh Feiz Disfani

Street address

Shahid Hasheminezhad Hospital, Andishe Street,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hamideh Feiz Disfani

Position

Assistant Professor of Emergency Medicine

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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Position

Assistant Professor of Emergency Medicine

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work
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Mashhad

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable