

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jul 2026

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

#### Protocol summary

##### 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

2018-04-15, 1397/01/26

##### 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

**City**  
Mashhad

**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

Commotio 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,  
Tolab boulevard, Mashhad, Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

1234567

**Phone**

+98 21 8670 5503

**Email**

feyzh@mums.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Tafaghodi

**Street address**

Ghoreyshi Building, Daneshgah Streets, Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

1234568

**Phone**

+98 21 8670 5503

**Email**

tafaghodim@mums.ac.ir

**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

**Street address**

Shahid Hasheminezhad Hospital, Andishe Street,  
Tolab boulevard, Mashhad, Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

1234568

**Phone**

+98 51 3123 4566

**Fax**

**Email**

Feyzh@mums.ac.ir

**Web page address**

**Person responsible for scientific 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

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Mashhad  
**Province**  
Razavi Khorasan  
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1234568  
**Phone**  
+98 51312345  
**Fax**  
**Email**  
feyzh@mums.ac.ir  
**Web page address**

**Province**  
Razavi Khorasan  
**Postal code**  
1234568  
**Phone**  
+98 21 8670 5503  
**Fax**  
**Email**  
feyzh@mums.ac.ir  
**Web page address**

## Person responsible for updating data

### 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  
**Street address**  
Shahid Hasheminezhad Hospital, Andishe Street,  
Tolab boulevard, Mashhad, Iran  
**City**  
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