

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Aug 2026

### Comparing the Antiemetic Effects of Ondansetron and Metoclopramide in Patients with Minor Head Trauma

#### Protocol summary

##### Summary

Nausea and vomiting are the most common complications after minor head trauma that increases the risk of intracranial pressure rising. This controlled, randomize, double blind clinical trial, will conduct in emergency department of Alzahra Hospital. The patients older than 15 years old with minor head trauma associated with nausea and vomiting will be randomly divided into 2 groups: treatment with metoclopramide (10mg/2ml, slow injection) and treatment with ondansetron (4mg/2ml, slow injection). The comparison between the 2 groups will be done regarding antiemetic efficacy and side effects.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015043012072N6**

Registration date: **2015-05-24, 1394/03/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-05-24, 1394/03/03

##### Registrant information

###### Name

Mehrdad Esmailian

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3629 3482

###### Email address

m\_esmailian@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2014-01-01, 1392/10/11

##### Expected recruitment end date

2014-06-30, 1393/04/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the Antiemetic Effects of Ondansetron and Metoclopramide in Patients with Minor Head Trauma

##### Public title

Ondancetron Effect at Vomiting Control in Head Trauma

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria : minor head trauma; nausea and vomiting; and a triage level of 3 or higher based on emergency severity score; exclusion criteria : hemodynamic instability; pregnancy/lactation; any neurologic deficit; restlessleg syndrome; alcohol usage; consumption of any antiemetic drugs during the 8 hours prior to admission; chemotherapy or radiotherapy; inability to complete and understand study explanations or outcome measures; allergy or previous adverse reactions to metoclopramide or ondansetron;

##### Age

From **15 years** old to **139 years** old

##### Gender

Both

##### Phase

4

## Groups that have been masked

No information

## Sample size

Target sample size: 120

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan University of Medical Sciences

##### Street address

Azadi Ave.

##### City

Isfahan

##### Postal code

#### Approval date

2013-08-06, 1392/05/15

#### Ethics committee reference number

65489

## Health conditions studied

### 1

#### Description of health condition studied

head Injuries

#### ICD-10 code

S06.9

#### ICD-10 code description

Intracranial injury, unspecified

### 2

#### Description of health condition studied

head Injuries

#### ICD-10 code

S09.9

#### ICD-10 code description

Unspecified injury of head

## Primary outcomes

### 1

#### Description

Nausea Severity

#### Timepoint

before drug injection and 20 minutes after drug injection

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

Dystonia

#### Timepoint

before drug injection and 20 minutes after drug injection

#### Method of measurement

Physical Examination

### 2

#### Description

Fatigue

#### Timepoint

before drug injection and 20 minutes after drug injection

#### Method of measurement

Physical Examination

### 3

#### Description

Headache

#### Timepoint

before drug injection and 20 minutes after drug injection

#### Method of measurement

Visual AnalogueScale

## Intervention groups

### 1

#### Description

Intervention group treat with ondansetron (4mg/2ml, slow injection). 20 minutes post drug administration, nausea level will measure again. If the severity of nausea not decrease at least by 20 mm compared to the rate before the treatment intervention, a rescue dose (4mg ondansetron) would be prescribed for the patient.

#### Category

Treatment - Drugs

### 2

#### Description

Cotrol group treat with metoclopramide (10mg/2ml, slow injection) and treatment with ondansetron (4mg/2ml, slow injection). 20 minutes post drug administration, nausea level will measure again.

#### Category

Treatment - Drugs

## Recruitment centers

1

**Recruitment center**

**Name of recruitment center**

Alzahra Hospital

**Full name of responsible person**

Mehrdad Esmailian

**Street address**

Sofeh Blv.

**City**

Isfahan

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Reza Azizkhani

**Street address**

Azadi Ave.

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Isfahan 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**

Isfahan University of Medical Sciences

**Full name of responsible person**

Mehrdad Esmailian

**Position**

Assistant Professor of Emergency Medicine

**Other areas of specialty/work**

**Street address**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Mehrdad Esmailian

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Assistant Professor of Emergency Medicine

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**Contact**

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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*