Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Mehrdad Esmailian
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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