

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparing the Effect of Ondansetron, Metoclopramide and Dexamethasone on Nausea in Patients with Mild Head Trauma Referred to Rasht Poursina Hospital

Protocol summary

Summary

Objectives: Objective of this study was to compare the effect of Ondansetron, Metoclopramide and Dexamethasone on nausea in patients with mild head trauma referred to Rasht Poursina Hospital. Design: The study design was randomized, double-blind and uncontrolled with placebo. Setting and conduct: The total number of patients was 102, who were divided into three groups of 34. They were injected with Metoclopramide, or Ondansetron and Dexamethasone. Nausea in these patients was evaluated by a nurse before drug injection based on the scoring criteria VAS (Visual Analogue Scale), then the medication was injected and after an hour, the nausea was re-evaluated. Patient's satisfaction score was 0 to 4. The number of the most common side effects for each drug was checked. Participants including major eligibility criteria: Patients with mild head trauma (without trauma in other body parts) and nausea that required injection with GCS arrival=15; age over 18 to 60 years; without metabolic and gastrointestinal diseases were included in the study. Patients with history of brain; internal and systemic disease; hemodynamic instability; pregnancy, alcohol use; chemotherapy or radiation therapy; pathological disorder and brain injury on CT scan were excluded. Intervention: Patients were injected with Metoclopramide, or Ondansetron and Dexamethasone. main outcome measures (variables): Nausea

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201605087369N4**

Registration date: **2016-06-05, 1395/03/16**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-06-05, 1395/03/16

Registrant information

Name

Firouz Behboudi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Guilan University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effect of Ondansetron, Metoclopramide and Dexamethasone on Nausea in Patients with Mild Head Trauma Referred to Rasht Poursina Hospital

Public title

Comparing the effect of Ondansetron, Metoclopramide and Dexamethasone on nausea in patients with mild head trauma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with mild head trauma and nausea that requires injection; with arrival GCS=15; age over 18 years to 60 years; the absence of metabolic and gastrointestinal diseases; only with head trauma: without other traumas Exclusion Criteria: Patients with history of brain; internal and systemic disease which mainly consists metabolic disorder such as kidney; liver and endocrine diseases; connective tissue diseases; vacuities and infectious diseases; hemodynamic instability; pregnancy; alcohol use; chemotherapy or radiation therapy; pathological disorder and brain injury on CT scan

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **102**

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 Guilan University of Medical Sciences

Street address

Vice Chancellor for Research and Technology of Guilan University of Medical Sciences, West Shahid Beheshti Blv, in front of Bank Sepah, Top floor of Iran Radiator agency, Rasht, Iran

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Postal code

Approval date

2016-02-02, 1394/11/13

Ethics committee reference number

IR.GUMS.REC.1394.452

Health conditions studied

1

Description of health condition studied

Mild head trauma

ICD-10 code

S00

ICD-10 code description

Superficial injury of head

Primary outcomes

1

Description

Nausea

Timepoint

Before and one hour after injection

Method of measurement

VAS scoring (Visual Analogue Scale)

Secondary outcomes

1

Description

Drug side effects

Timepoint

At discharg

Method of measurement

Clinical diagnosis

2

Description

Patient satisfaction

Timepoint

At discharg

Method of measurement

Questionnaire

Intervention groups

1

Description

Intravenous Ondansetron

Category

Treatment - Drugs

2

Description

Intravenous Metoclopramide

Category

Treatment - Drugs

3

Description

Intravenous Dexamethasone

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasht Poursina Hospital

Full name of responsible person

Rojin Jalal Safari

Street address

Rasht Poursina Hospital, Namjoo St, Rasht, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of
Guilan University of Medical Sciences

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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

Vice Chancellor for Research and Technology of Guilan
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

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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