

# 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

Gilan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 3336 8773

###### Email address

info@gtrc.ir

##### 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

##### **City**

Rasht

##### **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

###### City

Rasht

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

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

###### Full name of responsible person

Abtin Heidarzadeh

###### 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

###### City

Rasht

##### 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

#### Contact

##### Name of organization / entity

Guilan University of Medical Sciences

##### Full name of responsible person

Rojin Jalal Safari

##### Position

Medical student

##### Other areas of specialty/work

##### Street address

Guilan University of Medical Sciences, University of  
Guilan, 6 Km after Rasht-Tehran Highway, Rasht, Iran

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### Person responsible for scientific inquiries

#### Contact

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Behzad Zohrevandi

##### Position

Assistant Professor

##### Other areas of specialty/work

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### Person responsible for updating data

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##### Position

Medical Student

##### Other areas of specialty/work

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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*