

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The evaluation of effect of ondansetron and dexamethasone combination versus ondansetron alone on treatment of nausea and vomiting in patient with minor head trauma

#### Protocol summary

##### Study aim

Assessing the effect of ondansetron and dexamethasone combination versus ondansetron alone on treatment of nausea and vomiting in patient with minor head trauma

##### Design

A double-blind, randomized, double-blind, With two parallel groups case-control trial with a total of 64 patients referred to Khatam Hospital in year 98.

##### Settings and conduct

Initially, 64 patients with mild head trauma referred to Khatam hospital were randomly divided into two groups of control and case groups with use of blocked random numbers table. Therapist received two pre-filled syringes at the time of administration of the medication and therapist was unaware of the medication type. Patients in the control group received dexamethasone and ondansetron and in the case group patients received placebo and ondansetron .

##### Participants/Inclusion and exclusion criteria

The patients with head trauma and vomiting with GCS>14 that dont have shock signes and unstability.

##### Intervention groups

1. In the case group, the effect of ondansetron alone without dexamethasone(with placebo) on patients with mild head injury was evaluated 2.In the control group, the effect of ondansetron plus dexamethasone on mild head trauma patients in this group was evaluated.

##### Main outcome variables

Treatment of nausea and vomiting

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191127045526N1**

Registration date: **2020-04-12, 1399/01/24**

Registration timing: **retrospective**

Last update: **2020-04-12, 1399/01/24**

Update count: **0**

##### Registration date

2020-04-12, 1399/01/24

##### Registrant information

###### Name

Gholamreza Kargar shoraki

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3833 3549

###### Email address

kargar98@zaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2020-03-20, 1399/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The evaluation of effect of ondansetron and dexamethasone combination versus ondansetron alone on treatment of nausea and vomiting in patient with minor head trauma

##### Public title

Effect of ondansetron alone on brain contusion

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Head trauma with GCS>14 Head trauma with vomiting

### Exclusion criteria:

Patients with shock signes patients with gastrointestinal disease causing nausea

## Age

From 3 years old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider

## Sample size

Target sample size: 64

## Randomization (investigator's opinion)

Randomized

## Randomization description

Block randomization with four blocks, case group (A) and control group (B). Blocks list and numbers (1-6) are assigned to them. Then random numbers are used to determine the order of the blocks.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The therapist used pre-prepared medications without knowing what the medication was.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

##### Street address

No1, Jame Jam

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

98157733169

#### Approval date

2018-06-30, 1397/04/09

## Ethics committee reference number

IR.ZAUMS.REC.1397.157

## Health conditions studied

### 1

#### Description of health condition studied

Minor head trauma

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Nausea vomiting treatment

#### Timepoint

15 30 60 minutes after drug injection

#### Method of measurement

Patient evaluation in times 15 30 60 minutes after drug

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Ondansetron plus placebo group. In this group patients once received ondansetron 4mg plus placebo and then after one hour, patients were examined for nausea or vomiting.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: In the control group, patients were given ondansetron 4mg and dexamethasone 10mg and then patients were evaluated for nausea.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Khatam Hospital

##### Full name of responsible person

Dr.Gholamreza Kargar

##### Street address

No1,Jamejam Ave

##### City

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Zahedan University of Medical Sciences  
**Full name of responsible person**  
Dr.Gholamreza Kargar  
**Street address**  
No1,Jamejam Ave  
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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**  
Zahedan 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**  
Zahedan University of Medical Sciences  
**Full name of responsible person**  
Dr.Gholamreza Kargar  
**Position**  
Assistant  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Emergency Medicine  
**Street address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Zahedan University of Medical Sciences  
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Assistant  
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## Person responsible for updating data

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**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**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available