Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Iran (Islamic Republic of)

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+98 35 3833 3549

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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 Univercity of Medical Sciences

Street address

No1, Jame Jam

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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

Nausa vomiting treatment

Timepoint

15 30 60 minutes after drug injection

Method of measurement

Patient evaluation in times15 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

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No1,Jamejam Ave

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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