Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Ondansetron and Dexamethasone Versus Dexamethasone efficacy On Postoperative nausea and vomiting in patients with maxillofacial trauma

Protocol summary

Study aim

1. Comparison of Ondansetron and Dexamethasone versus Dexamethasone efficacy on postoperative nausea and vomiting in patients with maxillofacial trauma 2. Determining the frequency of nausea and vomiting in the intervention group and control group 3. Comparison of the frequency of nausea and vomiting in the intervention group and control by gender, age groups, duration of anesthesia and duration of surgery.

Design

Phase 1 triple-blind clinical trial with control group and one intervention group, and randomized by block randomization, is performed on 96 patients.

Settings and conduct

Patients are selected according to inclusion and exclusion criteria until the study is completed. The same treatment protocol is performed for all patients. Except that at the end of surgery for the intervention group, 8mg ondansetron IV is injected.

Participants/Inclusion and exclusion criteria

All patients referred to "Shohadaye Ashayer" hospital who have maxillofacial trauma and require surgery under general anesthesia are included. All patients who underwent another operation under general anesthesia 24 hours before maxillofacial surgery will be excluded from our study. Also patients with a history of Motion Sickness and recent vomiting, patients who are hypersensitive or allergic to any of the drugs studied, patients who have undergone surgery for severe hypotension and bradycardia, and need intraoperative blood transfusion or postoperative ICU They are out of action, they will be out of our study.

Intervention groups

At the end of surgery for the intervention group, ondansetron 8 mg will be injected through IV. No medication will be injected for the control group at the end of surgery.

Main outcome variables

Achieving the desired results means reducing nausea and vomiting without using additional drugs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190916044784N2**
Registration date: **2023-05-25, 1402/03/04**
Registration timing: **prospective**

Last update: **2023-05-25, 1402/03/04**
Update count: **0**

Registration date

2023-05-25, 1402/03/04

Registrant information

Name

Shahryar Bashirigoudarzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4415 7941

Email address

dr.s.bashiri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-08-22, 1402/05/31

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Ondansetron and Dexamethasone Versus Dexamethasone efficacy On Postoperative nausea and vomiting in patients with maxillofacial trauma

Public title
Comparison of Ondansetron and Dexamethasone Versus Dexamethasone efficacy On Postoperative nausea and vomiting in patients with maxillofacial trauma refered to "Shohadaye Ashayer" hospital of Khorramabad
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
All patients referred to the "Shohadaye Ashayer" Hospital who have maxillofacial trauma and require surgery under general anesthesia.
Exclusion criteria:
Patients who underwent another operation under general anesthesia 24 hours before maxillofacial surgery. Patients who have lost consciousness for any reason after trauma. Patients with ASA≥III. Patients with a history of Motion sickness or recent vomiting. Patients who have severe hypotension and bradycardia while surgery, and need intraoperative blood transfusion or postoperative ICU. Patients with hypersensitivity or allergy to any of the studied drugs.
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to equalize the production of individuals in the two groups, the Block Randomization method is used. Using this method, the sample size in the two study arms will be equal (balance).
Blinding (investigator's opinion)
Triple blinded
Blinding description
In order to blind the study, the severity of postoperative nausea and vomiting of patients is assessed by a person who is not aware of the study groups. Also, the patient and the person analyzing the study information are not aware of the drug injected for each patient.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Lorestan University of Medical Sciences
Street address
Lorestan School of Dentistry, Between Golshan 1,2 Ave., Shafipour Blvd.
City
Khorramabad
Province
Lorestan
Postal code
6816844168
Approval date
2022-03-09, 1400/12/18
Ethics committee reference number
IR.LUMS.REC.1401.001

Health conditions studied

1

Description of health condition studied
Maxillofacial trauma
ICD-10 code
S02
ICD-10 code description
Fracture of skull and facial bones

Primary outcomes

1

Description
Nausea and vomiting
Timepoint
1, 2, 6, 12 and 24 hours after surgery
Method of measurement
Direct questions from patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: For all the

studied patients, after entering the operating room (both the intervention group and the control group), an IV line will be installed. In order to prevent dehydration of patients, 500 cc of Ringer's serum is injected for each patient. Then, for all patients, pre-medication with midazolam in the amount of 2-3 mg and narcotic (fentanyl) in the amount of 2-4 cc (depending on the weight of the people) is done. After 3-5 minutes, induction of anesthesia begins. In all patients, propofol at the rate of 2-2.5 mg/kg, and atrocurium at the rate of 2.5 mg/kg as a muscle relaxant are used to induce anesthesia. Before surgery and during induction of anesthesia, 8 mg of dexamethasone is injected as an IV injection for all patients (whether in the intervention or control group). All subjects undergo nasal intubation 2-4 minutes after induction of anesthesia and injection of relaxant. After intubation, all people are connected to a mechanical ventilator. During surgery, anesthesia is maintained in all patients through TIVA and propofol will be injected at the rate of 0.1 mg/kg/minute. During the surgery, depending on the patient's needs (once every 35-45 minutes), the muscle relaxant will be repeated at the rate of 0.2 mg/kg. All patients are transferred to the recovery room after surgery, and the amount of nausea and vomiting as well as their possible side effects are recorded at intervals of 1, 2, 6, 12 and 24 hours after surgery. At the end of surgery, 8 mg of ondansetron is injected through IV injection for the intervention group.

Category

Prevention

2

Description

Control group: For the control group, no medicine is prescribed in addition to what was proposed as the main study protocol. After surgery, dexamethasone is injected for all patients on the first day at the rate of 2 doses per day and on the second day at the rate of 1 dose per day. In order to prevent disturbances in the treatment process of the patients, if nausea and vomiting of any of the patients (including from intervention and control group) was higher than one level, intervention and drug administration will be done to reduce or eliminate nausea and vomiting. This topic will be recorded in the questionnaire and study information.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Ashayer Hospital of Khorramabad

Full name of responsible person

Kosar Rostampur

Street address

Zomorrod 1 Apartment , Arasteh 6 Ave., Enghelab Blvd.

City

Khorramabad

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Lorestan

Postal code

6816844168

Phone

+98 66 3321 8502

Email

kosar_rostampur@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr. Bahram Rasoulian

Street address

Zomorrod 1 Apartment , Arasteh 6 Ave., Enghelab Blvd.

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Email

kosar_rostampur@yahoo.com

Grant name

Lorestan University of Medical Science

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Kosar Rostampur

Position

Student (Intern)

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

Zomorrod 1 Apartment , Arasteh 6 Ave., Enghelab Blvd.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Kosar Rostampur

Position

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Person responsible for updating data

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available