Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of prophylactic effects of intravenous metochlopramide and ondansetrone on postoperative nausea and vomiting (PONV) in maxillofacial surgery

Protocol summary

Summary

(1) Objectives: comparison of prophylactic effects of intravenous metochlopramide and ondansetrone on postoperative nausea and vomiting (PONV) in maxillofacial surgery (2) Design: randomized, double blind (3) Setting and conduct: patients alocated in 5 therapeutic groups and assessed at 6 intervals regarding nausea and vomiting. (4) Participants including major eligibility criteria: Participants will be selected from patients in Imam Reza hospital, who require maxillofacial surgery because of trauma or developmental problems. Inclusion criteria: 18-50 years of age; Patients undergoing IMF. Exclusion criteria: Systemic diseases affecting nausea and vomiting; Brain trauma in traumatic patients; Clinical conditions indicating presence of factors for being placed in a high risk group; Duration of surgery more than 3 hours; Use of nausea- and vomiting-inducing drugs such as opiates. (5) Intervention: Patients in group Oa will receive a single dose of ondansetrone (0.15 mg per kg) 30 minutes before the end of surgery. Patients in group Ob will receive a single dose of ondansetrone (0.15 mg per kg) 30 minutes before surgery. Patients in group Mb will receive a single dose of metochlopramide (0.5 mg per kg) 30 minutes before surgery. Patients in group Ma will receive a single dose of metochlopramide (0.5 mg per kg) 30 minutes before the end of surgery. Patients in group C (control group) will receive no prophylaxis and drugs before the end of surgery and metochlopramide will be routinely used PRN. (6) main outcome measures (variables): nausea, vomiting.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108147324N1**

Registration date: **2012-07-18, 1391/04/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-07-18, 1391/04/28

Registrant information

Name

Saeed Nezafati

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2011-06-22, 1390/04/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of prophylactic effects of intravenous metochlopramide and ondansetrone on postoperative

nausea and vomiting (PONV) in maxillofacial surgery

Public title
Prophylactic effects of ondansetrone
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: patients candidate for maxillofacial surgery; 18-50 years of age; Patients undergoing IMF. Exclusion criteria: systemic diseases affecting nausea and vomiting; brain trauma in traumatic patients, as a factor influencing nausea and vomiting; clinical conditions indicating presence of factors for being placed in a high risk group; duration of surgery more than 3 hours; use of nausea- and vomiting-inducing drugs such as opiates.
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **175**
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
Ethic committee of Tabriz university of medical sciences
Street address
Golgasht,Azadi street
City
Tabriz
Postal code
Approval date
2011-06-12, 1390/03/22
Ethics committee reference number
917

Health conditions studied

1

Description of health condition studied
Maxillofacial operations: trauma-orthognathic surgery
ICD-10 code
Y83.4
ICD-10 code description
Surgical operation and other surgical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description
Nausea
Timepoint
On arrival at the ward (full consciousness),Thirty minutes after full consciousness,An hour after full consciousness Thirty minutes after PO (nearly 4.5 hours after full consciousness),Eight hours after full consciousness,. Twenty hours after surgery
Method of measurement
Recorded by inspection of nausea and asking after recovery

2

Description
Vomiting
Timepoint
On arrival at the ward (full consciousness),Thirty minutes after full consciousness,An hour after full consciousness Thirty minutes after PO (nearly 4.5 hours after full consciousness),Eight hours after full consciousness,. Twenty hours after surgery
Method of measurement
recorded by inspection of vomiting

Secondary outcomes

1

Description
Vertigo
Timepoint
On arrival at the ward (full consciousness),Thirty minutes after full consciousness,An hour after full consciousness Thirty minutes after PO (nearly 4.5 hours after full consciousness),Eight hours after full consciousness,. Twenty hours after surgery
Method of measurement
Inspection and asking from the patient

Intervention groups

1

Description
Patients in group Ob will receive a single dose of ondansetrone (0.15 mg/kg) 30 minutes before surgery
Category
Treatment - Drugs

2

Description
Patients in group Oa will receive a single dose of ondansetrone (0.15 mg/kg) 30 minutes before the end of surgery
Category
Treatment - Drugs

3

Description
Patients in group Mb will receive a single dose of metochlopramide (0.5 mg/kg) 30 minutes before surgery.
Category
Treatment - Drugs

4

Description
Patients in group Ma will receive a single dose of metochlopramide (0. 5 mg/kg) 30 minutes before the end of surgery.
Category
Treatment - Drugs

5

Description
Patients in group C (control group) will not receive any prophylaxis and drugs before surgery or at the end of surgery and metochlopramide will be used PRN after surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of oral and maxillofacial surgery, Imam Reza hospital
Full name of responsible person
Dr. Saeed Nezafati
Street address
Golgasht Ave, Azadi street
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Alireza Ostadrahimi
Street address
Faculty of health and nutrition, Tabriz university of medical sciences< Golgasht, Azadi str
City
Tabriz
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, Tabriz 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
Tabriz university of medical sciences, Imam Reza hospital
Full name of responsible person
Dr. Hossein Dabbagh Asadolahi Pour
Position
dentist(DDS) , senior resident of OMFS
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
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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