Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The evaluation of pre-operative Clonidine versus Ondansetron prescription for control of pain, nausea & vomiting after Orthognathic surgery.

Protocol summary

Summary

objective: The aim of this study was to compare the effect of ondansetron and clonidine for pain, nausea and vomiting after orthosurgery. Study type: Randomized clinical trial. Inclusion criteria: All adult patients with ASA class I, II, age range between 18 and 40 years with jaw deformity Exclusion criteria: Patients who had experience of previous Ponv, nausea and vomiting in last 24 hours Patients known to be sensitive to clonidine and ondansetron Patients with history of low blood pressure and bradycardia Sample size: 40 patients (20 in each group) The main intervention: Intervention 1: Prescription of ondansetron (8 mg) in form of oral tablets that have been dissolved in 20 ml of water (as intervention) one hour before general anesthesia of orthosurgery Intervention 2: Prescription of clonidine (150 µg) in form of oral tablets that have been dissolved in 20 ml of water (as intervention) one hour before general anesthesia of orthosurgery Underlying variables: age, BMI, gender The main measurable outcomes: pain, nausea, vomiting immediately and up to first 24 hours after surgery. study time: 8 month

General information

Acronym

Clonidine versus Ondansetron in Orthognathic surgery.

IRCT registration information

IRCT registration number: **IRCT2017012922697N2**
Registration date: **2017-05-01, 1396/02/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-01, 1396/02/11

Registrant information

Name

Sahand Samiee rad

Name of organization / entity

mashhad dental school,oral and maxillofacial department

Country

Iran (Islamic Republic of)

Phone

+98 51 3883 7289

Email address

samieerads@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chanscellor for research Mashhad university of medical sciences. Oral and maxillofacial disease research center

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of pre-operative Clonidine versus Ondansetron prescription for control of pain, nausea & vomiting after Orthognathic surgery.

Public title

the evaluation of Clonidine versus Ondansetron for control of pain, nausea & vomiting after Orthognathic surgery.

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: All adult patients with ASA class I, II, age range between 18 and 40 years and BMI less than 30 kg per square meter, with jaw deformity and applicable for orthosurgery that referred to Mashhad dental school. Exclusion criteria: Patients with ASA III class and more. Patients with history of nausea in moving vehicles (Motion sickness) Patients who had experience of previous Ponv, nausea and vomiting in last 24 hours Patients with upper gastrointestinal disorders such as peptic ulcer disease, re flux, pyloric stenosis Patients with history of drug abuse and addiction Patients known to be sensitive to clonidine and ondansetron Patients with history of low blood pressure and bradycardia Patients who need to be care in ICU after surgery. Patients who not wish to continue participation in the program, for any reason.
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
As the effectiveness of clonidine or ondansetron in comparison with placebo for pain and PONV in surgical field is proved in other clinical trial studies; we decided to not have placebo in this study. Furthermore, the surgeon and anesthesiologist were aware of the drug types in order to prevent the peri and post operative complications; but the student who will record data and analyzing committee of information was blind. the patients were aware of the study interventions because of consent letter. Simple randomization (Random number table) will be used in this study.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad dental school of Mashhad university of medical sciences,
Street address
Ghoreishi building, Daneshghah avenue
City
Mashhad
Postal code
Approval date
2016-12-18, 1395/09/28
Ethics committee reference number
IR.mums.sd.REC.1394.176

Health conditions studied

1

Description of health condition studied
pain after orthosurgery
ICD-10 code
M25.5
ICD-10 code description
Pain in joint

2

Description of health condition studied
nausea and vomiting after orthosurgery
ICD-10 code
F50.5
ICD-10 code description
Vomiting associated with other psychological disturbances

3

Description of health condition studied
Jaw deformity
ICD-10 code
K07.9
ICD-10 code description
Dentofacial anomaly, unspecified

Primary outcomes

1

Description
amount of pain
Timepoint
1,3,6,12,24 hours after surgery.
Method of measurement
VAS

2

Description
nausea and vomiting amount after surgery
Timepoint
1,3,6,12,24 hours after surgery.
Method of measurement
yes or no / dose of rescue anti emetic drug

Secondary outcomes

1

Description
bradycardia
Timepoint
1,3,6,12,24 hours after surgery
Method of measurement
clinical observation

2

Description
blood pressure
Timepoint
1,3,6,12,24 hours after surgery
Method of measurement
clinical observation

Intervention groups

1

Description
Intervention 1:Prescription of ondansetron (8 mg) (150 µg) in form of oral tablets that have been dissolved in 20 ml of water (as intervention) one hour before general anesthesia of orthosurgery
Category
Treatment - Drugs

2

Description
Intervention 2:Prescription of clonidine (150 µg) in form of oral tablets that have been dissolved in 20 ml of water (as intervention) one hour before general anesthesia of orthosurgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Oral and maxillofacial surgery department,Mashhad dental school
Full name of responsible person
Dr sahand samiee rad
Street address
Mashhad dental school, Vakil abad boulvard
City
Mashhad

2

Recruitment center
Name of recruitment center
Oral and maxillofacial surgery department of Mashhad Qaem hospital
Full name of responsible person
Dr sahand samiee rad
Street address
Mashhad Qaem hospital, Ahmadabad boulvard
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research Mashhad university of medical sciences
Full name of responsible person
Dr Saeed Eslami
Street address
Ghoreishi building, Daneshghah avenue
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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
Vice chancellor for research Mashhad 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
oral and maxillofacial surgery department ,Mashhad dental school
Full name of responsible person
Dr Majid Eshghpour
Position
associate professor
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
oral and maxillofacial surgery department,mashhad dental school
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Dr Sahand samiee rad
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Assistant prof
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Person responsible for updating data

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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