Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of the effect of Preoperative administration of Dexmedetomidine on pain, nausea & vomiting after orthognathic surgery

Protocol summary

Study aim

evaluating the effect of Dexmedetomidine intravenous administration on pain degree, nausea, and vomiting in patients after bimaxillary orthognathic surgery.

Design

A randomized triple-blind clinical trial with a control group. The study design includes two parallel groups in the 3rd phase each including 30 patients. According to the table of random numbers, patients are classified into two groups. In group A, the drug, and in group B, the placebo will be prescribed

Settings and conduct

Oral and maxillofacial surgery department of Qaem hospital, Mashhad. The patients, the outcome assessor and data analyzer would not be aware of the drugs administered in each group.

Participants/Inclusion and exclusion criteria

The inclusion criteria: 1. Patients with skeletal class 3 deformity, aged from 18 to 40 years who are candidates for bimaxillary orthodontic surgery (maxillary advancement using Lefort 1 osteotomy and mandibular setback surgery by bilateral sagittal split osteotomy (BSSO)) 2. Body Mass Index less than 30 kg / m2 3. Complete the informed consent The Exclusion criteria: 1. Patients with a history of drug allergy, Motion Sickness, addiction or psychological problems and hypotension and bradycardia 2. Patients with upper gastrointestinal problems such as gastric ulcer, reflux, pyloric stenosis

Intervention groups

In the intervention group, dexmedetomidine is administered intravenously with an induction dose of 1 µg / kg and a maintenance dose of 0.2 µg/kg.h، twenty minutes before the start of orthognathic surgery anesthesia. In the control group, a placebo (Normal Saline 0/9%) is administered similarly to the intervention group.

Main outcome variables

The degree of pain will be assessed using the Visual Numerical Scale (VAS), the presence or absence of nausea and vomiting will be evaluated immediately and 1 hour, 3 hours, 6 hours, 12 hours, and the 24 hours postoperatively

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150613022697N9**
Registration date: **2020-12-04, 1399/09/14**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-04, 1399/09/14**
Update count: **0**

Registration date

2020-12-04, 1399/09/14

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

Expected recruitment start date

2020-10-21, 1399/07/30

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Preoperative administration of Dexmedetomidine on pain, nausea & vomiting after orthognathic surgery

Public title

The effect of dexmedetomidine on pain, nausea and vomiting following orthognathic surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between the ages of 18 and 40 Patients with skeletal class 3 deformity who are candidates for bimaxillary orthodontic surgery (maxillary advancement using Lefort 1 osteotomy and mandibular setback surgery by bilateral sagittal split osteotomy (BSSO)) Patients with a Body Mass Index of less than 30 kg / m2 Patients who have completed the informed consent

Exclusion criteria:

Patients with a history of drug allergy Patients with a history of Motion Sickness Patients with a history of addiction or psychological problems Patients with a history of hypotension and bradycardia Patients with upper gastrointestinal problems such as gastric ulcer, reflux, pyloric stenosis

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Since the two groups are supposed to have the same sample size, Patients eligible for inclusion will be divided into 2 groups using the Blocked Randomization method by one of the nurses of the relevant ward, who is not aware of the implementation of the study. Random sequences will be generated using the Random Generator program. Based on the random block method, 15 blocks of four-block will be generated for 60 patients. Random allocation concealment will be done using sequentially numbered, sealed, opaque envelopes by an independent person who does not know the study process.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, the patient, surgeon, outcome assessor, and statistical analyzer will not be aware of the study groups. Regarding patients, blinding is so that patients will not know if they will receive a drug or a placebo. Regarding the assessor, the operator who delivers the pain questionnaires to the patient and completing the study checklist is not aware of the group assignment. The statistical analyzer will be blinded and all data will be provided in the form of coding to him. Furthermore, the anesthesiologist was aware of the drug types in order to prevent the peri- and postoperative complications.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Science

Street address

Ghoreishi building, Daneshghah avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2020-09-02, 1399/06/12

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1399.056

Health conditions studied

1

Description of health condition studied

Acute pain

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

2

Description of health condition studied

Nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description
Pain degree
Timepoint
1 hour, 3 hours, 6 hours, 12 hours, and 24 hours postoperatively
Method of measurement
Visual analogue scale (VAS) for pain

2

Description
Presence or absence of nausea
Timepoint
Immediately after recovery and 1 hour, 3 hours, 6 hours, 12 hours, and 24 hours postoperatively
Method of measurement
scoring (0=non, 1=nausea)

3

Description
Presence or absence of vomiting
Timepoint
Immediately after recovery and 1 hour, 3 hours, 6 hours, 12 hours, and 24 hours postoperatively
Method of measurement
scoring (0=non, 1=vomiting, 2=vomiting >2 times)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, dexmedetomidine vial made by Hospira Co. with the brand name of Precedex, Will be administered intravenously with an induction dose of 1 µg/kg and a maintenance dose of 0.2 µg/kg.h، twenty minutes before the start of orthognathic surgery anesthesia.
Category
Treatment - Drugs

2

Description
Control group: In the control group, Normal Saline 0.9% with the volume equal to a dose of Dexmedetomidine will be administered intravenously, twenty minutes before the start of orthognathic surgery anesthesia.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Oral and maxillofacial surgery department of Qaem hospital , Mashhad
Full name of responsible person
Sahand Samieerad
Street address
School of Dentistry, Park Square, Mashhad
City
Mashhad
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Razavi Khorasan
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9176999311
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+98 51 3840 0000
Email
samieerads@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
Street address
Ghoreishi building, Daneshghah avenue.
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Email
TafaghodiM@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Sahand Samieerad
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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Oral and maxillofacial surgery department, Mashhad dental school, Vakil abad street.
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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person
Ali Labafchi
Position
Student
Latest degree
Medical doctor
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+98 51 3882 9525
Email
Labafchia941@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All collected data would be shared for all researchers after the participants were unidentified.
When the data will become available and for how long
The access to data will be started 6 months after publication
To whom data/document is available
The data would only be available for people working in academic institutions.
Under which criteria data/document could be used
It is allowed to use the data for meta-analysis and systematic reviews.
From where data/document is obtainable
The data can be obtained via email, from the corresponding researches (Dr Sahand samiee rad). E-mail: samieerads@mums.ac.ir
What processes are involved for a request to access data/document
The new research proposal and the processes details should be e-mailed to corresponding researcher in order

to get the access permission

Comments