Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 2026

Comparison of opioid requirement and pain intensity after mandibular surgeries in intraoperative infusion and bolus injection during dexmedetomidine extubation: a randomized clinical trial

Protocol summary

Study aim
Comparison of opioid requirement and pain intensity after mandibular surgeries in intraoperative infusion and bolus injection during dexmedetomidine extubation: a randomized clinical trial

Design
A clinical trial with parallel intervention groups, double-blind, randomized, on 40 patients. The sampling method is random. Randomization using a table of random numbers is the Random Allocation Software.

Settings and conduct
Among the patients referred to the Maxillofacial Surgery Department of Imam Reza Hospital In Tabriz who are candidates for mandibular surgery, they participate in the study. Patients are randomly assigned to one of the groups. In the first group, after surgery and before extubation, dexmedetomidine will be infused at the rate of 5.0 mg/kg, and in the second group, it will be injected exactly like the first group, but by bolus method. The intensity of pain during recovery, the first, second, fourth, sixth, twelfth, and twenty-fourth hours after discharge from recovery will be measured using VAS. Also, the number of times needed for opioid medication will be recorded if the pain intensity of the patients is higher than 5. The researcher is aware of the existence of two types of treatment, but he does not know which method of medicine he received in each group. Data analysts are not aware of the type of intervention.

Participants/Inclusion and exclusion criteria
Including criteria: candidate for mandibular surgery, duration of surgery less than 4 hours Excluding criteria: sensitivity to dexmedetomidine, non-cooperation in the study

Intervention groups
Intervention 1: Injection of dexmedetomidine infusion after surgery Intervention 2: bolus injection of dexmedetomidine after surgery

Main outcome variables
The amount of pain؛ frequency of needing opioids

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220819055746N1**
Registration date: **2022-08-29, 1401/06/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-29, 1401/06/07**
Update count: **0**

Registration date
2022-08-29, 1401/06/07

Registrant information
Name
Loghman Ebrahimi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-08-20, 1401/05/29
Expected recruitment end date
2022-09-30, 1401/07/08
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of opioid requirement and pain intensity after mandibular surgeries in intraoperative infusion and bolus injection during dexmedetomidine extubation: a randomized clinical trial

Public title

The effect of dexmedetomidine in reducing pain after jaw surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age above 18 years Candidate for mandibular surgery Consent to participate in the study

Exclusion criteria:

History of allergy to dexmedetomidine Multi-trauma patients Addiction to drugs and psychoactive substances History of taking antidepressants History of previous mandible, maxilla and cheek surgery during the last three months Patients diagnosed with rheumatoid arthritis Patients with kidney and liver diseases Dialysis patients Patients receiving anticoagulant drugs Patients with a history of systemic infections Patients with hemostatic disorders

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random sampling will be done among the patients referred to the maxillofacial surgery department of Imam Reza Hospital in Tabriz who are eligible for the study. The randomization method is simple and its unit is individual. Random numbers are our tool for randomizing. Based on this, the type of treatment is marked with code A (infusion) and B (bolus) and placed inside sealed envelopes. Then the envelopes are placed in a bag and mixed. Then it is randomly selected from the bag and treatment is given to the patient by observing the code. None of the patients will be informed about the treatment of another patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind. The injection will be done by an anesthesiologist. The researcher who will conduct the evaluation will not know about the type of intervention performed. Also, the person analyzing the data will be unaware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Golgasht St., Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2022-06-27, 1401/04/06

Ethics committee reference number

IR.TBZMED.REC.1401.308

Health conditions studied

1

Description of health condition studied

Fracture of mandible

ICD-10 code

S02.6

ICD-10 code description

Fracture of mandible

Primary outcomes

1

Description

Pain intensity

Timepoint

during recovery, the first, second, fourth, sixth, twelfth and twenty-fourth hours after discharge from recovery

Method of measurement

Visual Analogue Scale

2

Description

The amount of using opioid

Timepoint

during recovery, the first, second, fourth, sixth, twelfth

and twenty-fourth hours after discharge from recovery

Method of measurement

The amount of pain during recovery is measured in the first, second, fourth, sixth, twelfth and twenty-fourth hours after discharge from recovery. If the Visual Analogue Scale is higher than 5, pethidine (Exir-Iran company) at the rate of 1 mg/kg will be injected intramuscularly. After four hours, in case of recurrence of pain, the pethidine injection will be repeated at the rate of 1mg/kg. The number of times the patient needs pethidine in twenty-four hours will be recorded.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After surgery and before extubation, 5.0 mg/kg of dexmedetomidine will be infused. VAS will be measured. Also, the number of times needed for opioid medication will be recorded if the pain intensity of the patients is higher than 5.

Category

Treatment - Drugs

2

Description

Intervention group: After surgery and before extubation, 5.0 mg/kg dexmedetomidine will be injected by bolus method. Pain intensity during recovery, first, second, fourth, sixth, twelfth, and twenty-fourth hours after discharge from Recovery will be measured using VAS. Also, the number of times needed for opioid medication will be recorded if the pain intensity of the patients is higher than 5.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Tabriz Hospital

Full name of responsible person
Saeed Nezafati

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Golgasht St., Tabriz University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mozhgan Kachuei

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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Saeed Nezafati

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be 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
Not applicable
Data Dictionary
Not applicable