Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

The effect of Dexmedtomidine plus Bupivacaine on postoperative pain in mandibular third molar Surgery.

Protocol summary

Study aim
The purpose of this study is to evaluate the effect of Dexmedetomidine plus Bupivacaine on postoperative pain in mandibular third molars surgery.

Design
Double blind randomized clinical trial with control group.60 patient between October 2019 and October 2020

Settings and conduct
This study is performed at Shahid Beheshti Dental School. Patients are asked for pain by visual analogue scale 4, 8 and 12 hours after surgery (mild: 1-3 moderate: 4-6 sever 7-10)and also taking or not taking Ibuprofen during the next 12 hours, if taken analgesic, it is classified as severe pain.

Participants/Inclusion and exclusion criteria
Patients undergoing Class B-2 mandibular third molar surgery with ASA status I and age range 18 to 36 years who are referred to Shahid Beheshti Dental School enter the study and patients with drug addiction and using psychological drugs and have tooth decay in the study quadrant or the female patients in the menus period are excluded.

Intervention groups
Sixty patients in the study are divided equally into two groups. Both groups undergo impacted third molar removal. Both groups receive 400 mg ibuprofen one hour before surgery. In the intervention group, inferior mandibular block injection with Bupivacaine% 0/5 and Epinephrine 1: 200000 with 0.5 mg / kg Dexmedetomidine is injected after completion of surgery. In control group injection of inferior mandibular block injection with 1.8 ml Bupivacaine 0.5% with epinephrine 1: 200000 after Surgery is performed but Dexmedetomidine is not injected.

Main outcome variables
Patients degree of pain at 4, 8, and 12 hours after surgery and taking or not taking Ibuprofen during 12 hours after surgery.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190819044566N1**
Registration date: **2019-09-18, 1398/06/27**
Registration timing: **prospective**

Last update: **2019-09-18, 1398/06/27**
Update count: **0**

Registration date
2019-09-18, 1398/06/27

Registrant information

Name
Pegah Mehrabi nia

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4441 8360

Email address
pegahmehrabinia@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-22, 1398/07/30

Expected recruitment end date
2020-10-21, 1399/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of Dexmedtomidine plus Bupivacaine on postoperative pain in mandibular third molar Surgery.

Public title
Effect of Dexmedtomidine on postoperative pain in third molar surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with impacted wisdom tooth (Mesioangular, class II B in Pel and Gregory classification) 18 to 30 years old ASA I status Referred to Shahid Beheshti Dental School for Surgery and willing to be enrolled in the study
Exclusion criteria:
Patients who receive psychological drugs or have drug addiction More than one tooth surgery or other dental treatments such as root canal therapy Impact tooth in other categories of Pel and Gregory classification Refuse to study enrollment Women in menses
Age
From **18 years** old to **30 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, random allocation software was used for simple randomization.after allocation in 2 groups with 20 persons, concealed in sequentially numbered, sealed, opaque envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
After informing patients of their study and consenting to this study, they are divided into two groups to reduce bias for intervention and outcome evaluation in a double-blind manner so that patients are divided into two groups of one and two without knowledge of membership in which group, they receive surgery. Neither the study nor the observer knows who will be in which group.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University Of Medical Sciences, A'arabi St., Daneshjou Blv., Velenjak, Tehran
City
Tehran
Province
Tehran
Postal code
1469733476
Approval date
2017-10-29, 1396/08/07
Ethics committee reference number
IR.SBMU.RIDS.REC.1396.573

Health conditions studied

1

Description of health condition studied
Post dental surgery pain
ICD-10 code
G89.18
ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Post surgical pain
Timepoint
4, 8, 12 hours after surgery
Method of measurement
The pain severity is measured using visual analogue scale by asking patients: 0-10 (0-3 mild, 4-6 moderate and 7-10 sever which subjects need pain relief drugs).

2

Description
The amount of analgesics that is used by patients
Timepoint
Consumption of analgesic within 12 hours after surgery
Method of measurement
Asking patients

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: subjects receive a mixture of Bupivacaine 0.5% (1.8 ml) with epinephrine 1:200000 (Novocal Pharmucautical of Canada Inc. Cambridye, Ontario N1R6) and 0.5 mg/kg Dexmedetomidine (Exir co, Iran) through the inferior alveolar nerve block injection and immediately after surgeries.All subjects receive 400 mg Ibuprofen 1 hour before surgeries.

Category

Treatment - Drugs

2

Description

Control group:1.8 ml Bupivacaine 0.5% and Epinephrine 1:200000 is injected after surgeries for all subjects. All subjects receive 400 mg Ibuprofen 1 hour before surgeries.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti dental school

Full name of responsible person

Hasan Mir Mohammad Sadeghi

Street address

Shahid Beheshti University of Medical Sciences, A'arabi St., Daneshjou Blv., Velenjak, Tehran,Iran.

City

Tehran

Province

Tehran

Postal code

1469733476

Phone

+98 21 4441 8390

Email

Pegahmehrabinia@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Pegah Mehrabi Nia

Street address

Shahid Beheshti University of Medical Sciences, A'arabi St., Daneshjou Blv., Velenjak, Tehran,Iran.

City

Tehran

Province

Tehran

Postal code

1469733476

Phone

+98 21 4441 8390

Email

pegahmehrabinia@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Pegah Mehrabi Nia

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Shahid Beheshti University of Medical Sciences, A'arabi St., Daneshjou Blv., Velenjak, Tehran,Iran.

City

Tehran

Province

Tehran

Postal code

1469733476

Phone

+98 920 510 6983

Email

pegahmehrabinia@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Pegah Mehrabi Nia

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Shahid Beheshti University of Medical Sciences, A'arabi St., Daneshjou Blv., Velenjak, Tehran,Iran.

City

Tehran

Province

Tehran

Postal code

1469733476

Phone

+98 920 510 6983

Email

pegahmehrabinia@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Pegah Mehrabi Nia

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Shahid Beheshti University of Medical Sciences, A'arabi St., Daneshjou Blv., Velenjak, Tehran,Iran.

City

Tehran

Province

Tehran

Postal code

1469733476

Phone

+98 920 510 6983

Email

pegahmehrabinia@yahoo.com

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

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

Undecided - It is not yet known if there will be 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