

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### The effect of Dexmedetomidine 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 Pharmaceutical of Canada Inc. Cambridge, 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.

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**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.

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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**

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

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**Contact**

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student

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Position**

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**Latest degree**

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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**

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