Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The comparison of Rupivacain versus Lidocain effect on intraoperative bleeding and pain, and postoperative pain after wisdom tooth surgery

Protocol summary

Study aim
Comparison of the efficacy of ropivacaine on intraoperative and postoperative factors of an impacted third mandibular molar with lidocaine with epinephrine

Design
Controlled clinical trial with parallel groups, single-blind, randomized

Settings and conduct
Department of Oral and Maxillofacial Surgery, Mashhad Dental School. The patient, the outcome assessor, and the data analyst are unaware of the type of drug being injected in either direction.

Participants/Inclusion and exclusion criteria
Inclusion criteria: ASA I or ASA II; informed consent; age between 18-30 years; two wisdom teeth (mesioangular impaction, level B, class 1 or 2) which are similar in terms of surgical severity; no general contraindications (low blood pressure, bradycardia, sinus disorder, unstable high blood pressure, arousability, tachyphylaxis and liver disorders); No lesions and malignancies at the surgical site; No smoking. Exclusion criteria: wisdom tooth surgery on one side; occurring medical problems during surgery, need more than one cartridge injection, surgery lasting more than 20 minutes.

Intervention groups
Patients who require mandibular wisdom tooth surgery on both sides are included in the study and undergo split-mouth surgery under the anesthesia of ropivacaine and lidocaine. Lidocaine will be injected on one side and ropivacaine on the other.

Main outcome variables
Bleeding during surgery, the amount of pain during and after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181023041425N3**
Registration date: **2021-12-06, 1400/09/15**
Registration timing: **prospective**

Last update: **2021-12-06, 1400/09/15**
Update count: **0**

Registration date
2021-12-06, 1400/09/15

Registrant information

Name
Majid Hosseini Abrishami

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-31, 1400/10/10

Expected recruitment end date
2022-03-20, 1400/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison of Rupivacain versus Lidocain effect on intraoperative bleeding and pain, and postoperative pain after wisdom tooth surgery

Public title

The comparison of Rupivacain versus Lidocain effect on intraoperative bleeding and pain, and postoperative pain after wisdom tooth surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

According to the ASA physical status classification system, patient should be ASA I or ASA II (normal healthy patient or patient with mild systemic disease) Patient with informed consent. Patient's age should be between 18-30 years. Patients should have two wisdom teeth (classified in the same class by Pell & Gregory; mesioangular impaction, level B, class 1 or 2), which are similar in terms of surgical severity No general contraindications (patients with low blood pressure, bradycardia, sinus disorder, unstable high blood pressure, arousability, tachyphylaxis and liver disorders.) No lesions and malignancies at the surgical site; No smoking.

Exclusion criteria:

Patient with wisdom tooth surgery on one side Patient who needs more than one cartridge injection Occurring medical problems during surgery; Surgery lasting more than 20 minutes.

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **2**

Left and right mandibular impacted third molar

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization steps are as followed: for the first patient, two envelopes with the same appearance are selected, inside one of them there is a card on which dexmedetomidine in ropivacaine, and inside the other is a card on which lidocaine is written. After that, the surgeries are performed alternately. (Note that if for the first patient, surgery is performed by the ropivacaine; for the opposite tooth surgery, lidocaine will be used and vice versa.)

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study blinded groups involves patients and persons who analyses the data. Participants will be unaware of the fact that they receive Rupvacaine or Lidocaine in which side (of course during signing moral Satisfaction form ,they will be notified if they receive both of these two drugs.)

Placebo

Not 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 Sciences

Street address

Mashhad University of Medical Science, Daneshgah Ave, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2019-12-25, 1398/10/04

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1398.119

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

intraoperative bleeding

ICD-10 code

R58

ICD-10 code description

Hemorrhage, not elsewhere classified

Primary outcomes

1

Description

Evaluate the amount of pain after surgery

Timepoint

2 hour, 6 hours, 12hours, 18 hours, and 24 hours postoperatively

Method of measurement
Visual analogue scale (VAS) for pain

2

Description
The amount of surgical bleeding
Timepoint
at the end of surgery
Method of measurement
Blood in suction and gauze

3

Description
Evaluate the amount of pain during surgery
Timepoint
After flap removal, after osteotomy, and after tooth extraction
Method of measurement
Visual analogue scale (VAS) for pain

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: includes group that received 2cc Ropivacaine 0/5% (naropin) as preoperative anesthesia
Category
Treatment - Drugs

2

Description
Control group: includes group that received 1/8cc Lidocaine 2% with epinephrine 1/80000 (Persocaine) as preoperative anesthesia
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
oral and maxillofacial department of mashhad dental school
Full name of responsible person
majid hoseini abrishami
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
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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
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
Majid Hosseini Abrishami
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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