Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

Evaluation of patient's sedation and surgeon's satisfaction by applying the combination of Dexmedetomidine and Lidocaine during wisdom tooth surgery

Protocol summary

Study aim
Evaluation of patient's sedation and surgeon's satisfaction by applying the combination of Dexmedetomidine and Lidocaine during wisdom tooth surgery

Design
Controlled clinical trial with parallel groups, double-blind, randomized, Target sample size is 26 persons (each person has 2 samples), So total sample size is 52.

Settings and conduct
Among the patients referred to Isfahan surgery department for wisdom tooth surgery in 2020, 26 patients eligible for inclusion is randomly selected. The type of anesthesia is determined randomly in the first surgery and isn't told to the surgeon prior to the finishing of the surgical procedure. The patient and evaluator are blind about the type of anesthesia.

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
In the intervention group, 10µg dexmedetomidine in combination with lidocaine 2% with epinephrine 1/80000 is applied for anesthesia. In the control group lidocaine 2% with epinephrine 1/80000 is used.

Main outcome variables
Patient's sedation ; Surgeon's satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200406046966N1**
Registration date: **2020-04-18, 1399/01/30**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-18, 1399/01/30**
Update count: **0**

Registration date
2020-04-18, 1399/01/30

Registrant information

Name
Kimia Salimian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 38 3222 5786

Email address
kimia.slmn@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-08, 1399/01/20

Expected recruitment end date
2020-05-09, 1399/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of patient's sedation and surgeon's satisfaction by applying the combination of Dexmedetomidine and Lidocaine during wisdom tooth surgery

Public title
Effect of Dexmedetomidine on patient's sedation and surgeon's satisfaction during wisdom tooth surgery

Purpose
Supportive

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 (in these patients use of dexmedetomidine is contraindicated: 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; Occurring medical problems during surgery; Patient who needs more than one cartridge injection; 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
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **26**
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 combination with lidocaine is written, and inside the other is a card on which lidocaine alone is written. Before the surgery, surgeon randomly selects one of the envelopes and only the researcher knows the content of envelope and the type of anesthesia isn't told to the surgeon prior to the start of injection and finishing the surgical procedure. After that, the surgeries are performed alternately. (Note that if for the first patient, surgery is performed by the combination of dexmedetomidine and lidocaine; for the opposite tooth surgery, lidocaine alone will be used and vice versa.)

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, both participants and surgeon aren't aware of the type of anesthetic medications (in the other words, surgeon doesn't know for which patient uses the combination of dexmedetomidine and lidocaine or lidocaine alone) and only the researcher is aware of the cartridge combination. So, this study is double blinded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Hezar jarib St., Isfahan university of medical sciences

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2020-04-04, 1399/01/16

Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.009

Health conditions studied

1

Description of health condition studied
Mandibular impacted wisdom tooth

ICD-10 code
K01.1

ICD-10 code description
Impacted teeth

Primary outcomes

1

Description
The patient's sedation rate

Timepoint
After the intervention
Method of measurement
Short Dental Fear Questionnaire

2

Description
Surgeon's satisfaction.
Timepoint
After the intervention
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Patient's cooperation level
Timepoint
After the intervention
Method of measurement
Data collection form

2

Description
Evaluation of patient's satisfaction
Timepoint
After the intervention
Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group: In the intervention group, the patient undergoes local anesthesia with 10µg dexmedetomidine in combination with lidocaine 2% with epinephrine 1/80000. Cartridges are from Eksir brand. Each vial of Dexmedetomidine contains 2 ml (200µg) of the drug. /1 cc of each vial contains 10 µg of drug which is added to the cartridge of the intervention group with insulin syringe. Cartridges containing dexamedetomidine and lidocaine are similar to cartridges of lidocaine in terms of transparency.
Category
Treatment - Drugs

2

Description
Control group: The control group undergoes local anesthesia with lidocaine 2% with epinephrine 1/80000. Cartridges are from Eksir brand. To equalize the volume and appearance of the cartridges, /1 cc of normal saline is added to the cartridge of control group. Cartridges containing dexamedetomidine and lidocaine are similar to cartridges of lidocaine in terms of transparency.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Dental School
Full name of responsible person
Dr.Milad Etemadi
Street address
Department of Oral and Maxillofacial Surgery, School of Dentistry, Isfahan University of Medical Sciences, Hezarjarib St., Isfahan
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Isfahan
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Isfehan
Postal code
8174673461
Phone
+98 31 3792 5554
Email
etemadi@dnt.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr.Nakisa Torabinia
Street address
Vice Chancellor for Research of School of Dentistry, Isfahan Unuversity of Medical Sciences, Hezarjarib St., Isfahan
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Torabinia@dnt.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Milad Etemadi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Department of Oral and Maxillofacial Surgery, School of Dentistry, Isfahan University of Medical Sciences, Hezarjarib St., Isfahan

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Milad Etemadi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Kimia Salimian

Position

Dentistry Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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8816736571

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kimia.slmn@gmail.com

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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after patients are unrecognizable.

When the data will become available and for how long

6 months after the publication of the article

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Use of data under the supervision and agreement of the Isfahan University of Medical Sciences vice chancellor of Research and Technology and the project implementer and to achieve the intended aims in the proposal and developing review studies

From where data/document is obtainable

Dr.Milad Etemadi: etemadi@dnt.mui.ac.ir

What processes are involved for a request to access data/document

1-Contact the project implementer via Email and make a written request for the consent to deliver the data 2-Seeking contact information of Isfahan University of Medical Sciences Vice Chancellor of research and Technology 3-Make a written request to obtain permission from Isfahan University of Medical Sciences Vice Chancellor of research and Technology 4-The data can be accessed only in person from the Department of Oral and Maxillofacial Surgery of Isfahan Dental School. If there is no problem, data will be accessible in 2 weeks.

Comments