

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The comparative evaluation of maxillary infiltration and mandibular block injection effect on the cardiovascular parameters with 2 different local anesthesia solutions, Lidocaine and prilocaine in Patients Requiring Restorative Treatment of molar Teeth

Protocol summary

Study aim

The Comparison of maxillary infiltration and mandibular block injection effect on the cardiovascular parameters with 2 different local anesthesia solutions, Lidocaine and prilocaine

Design

Clinical trials with Parallel, Double blind, randomized groups

Settings and conduct

112 patients referring to the dental school of Kermanshah University of Medical Sciences will be chosen. Patients are randomly divided into four groups, Groups included: 1. Block injection in mandible with 2% lidocaine solution with epinephrine 1: 80,000, 2. infiltration injection in maxilla with lidocaine 2% solution with epinephrine 1: 80,000, 3. Block injection in mandible with prilocaine solution, 4. infiltration injection in maxilla with prilocaine solution. Systolic and diastolic blood pressure and heart rate and blood oxygen saturation percentage will be evaluated, In the four stages. A dark tape will cover each anesthetic cartridge.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People aged 20-50 years, Have general health, needing restorative treatment of maxillary or mandibular molar teeth. Exclusion criteria: medical history of cardiovascular, hypertension, Diabetes, kidney diseases, gastrointestinal bleeding or ulceration, Use of medications that make disturbance in function of anesthetic substance, Patients with pathology problems at the injection site, pregnant and nursing patients

Intervention groups

Block injection in mandible with 2% lidocaine solution with epinephrine 1: 80,000, infiltration injection in maxilla with lidocaine 2% solution with epinephrine 1: 80,000, Block injection in mandible with prilocaine 3% solution, infiltration injection in maxilla with prilocaine

3% solution

Main outcome variables

Level of systolic blood pressure, Level of diastolic blood pressure, Heart rate per minute, Peripheral blood oxygen saturation percentage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140527017880N6**

Registration date: **2018-05-12, 1397/02/22**

Registration timing: **prospective**

Last update: **2018-05-12, 1397/02/22**

Update count: **0**

Registration date

2018-05-12, 1397/02/22

Registrant information

Name

Roohollah Sharifi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1722 2400

Email address

r.sharifi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-20, 1397/02/30
Expected recruitment end date
 2018-06-20, 1397/03/30
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 The comparative evaluation of maxillary infiltration and mandibular block injection effect on the cardiovascular parameters with 2 different local anesthesia solutions, Lidocaine and prilocaine in Patients Requiring Restorative Treatment of molar Teeth

Public title
 The Comparison of maxillary infiltration and mandibular block injection effect on the cardiovascular parameters with 2 different local anesthesia solutions

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 People aged 20-50 years Have general health needing restorative treatment of maxillary or mandibular molar teeth
Exclusion criteria:
 Patients with medical history of cardiovascular, hypertension, Diabetes, kidney diseases, gastrointestinal bleeding or ulceration Use of medications that make disturbance in function of anesthetic substance Patients with pathology problems at the injection site pregnant and nursing patients

Age
 From **20 years** old to **50 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
 Target sample size: **112**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Randomization tools are sealed envelopes. Random unit is of individual type. Randomization is a simple way so that numbness cartridges are covered by covers and for each type of numbness we consider one of the numbers 1 and 2 and write the considered number on the cartridges covered with the covers (Each number represents a particular type of anesthetic substance). Then the patient chooses one of these cartridges. These cartridges are provided to patients who visit the Dental

Clinics of Kermanshah from May 20, 2018 to June 20, 2018 for restoration of the molar teeth. Placing covers and writing numbers is done only by one of the researchers, so the injector, the evaluator and the participant, are unaware of the type of anesthesia.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 Both anesthetics used in the study are safe and do not pose a risk to patients. Before doing the study, written consent is taken from the patients. One of the cartridges covered with a cover that one of the numbers 1 and 2 is written on it, Is selected by the patient (Each number represents a particular type of anesthetic substance). Placing covers and writing numbers is done only by one of the researchers, so the injector, the evaluator and the participant, are unaware of the type of anesthesia.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Ethics Committee of Kermanshah University of Medical Sciences

Street address
 Ethics Committee of Kermanshah University of Medical Sciences, Shahid Beheshti Blvd

City
 Kermanshah

Province
 Kermanshah

Postal code
 67146673159

Approval date
 2017-10-25, 1396/08/03

Ethics committee reference number
 ir.kums.rec.1396.389

Health conditions studied

1

Description of health condition studied
 Local anaesthetics

ICD-10 code
 Y48.3

ICD-10 code description
 Local anaesthetics

Primary outcomes

1

Description

Level of systolic blood pressure

Timepoint

10 minutes before injection, immediately after injection,
10 minutes after injection, 20 minutes after injection

Method of measurement

automatic brachial pressure gauge device

2

Description

Level of diastolic blood pressure

Timepoint

10 minutes before injection, immediately after injection,
10 minutes after injection, 20 minutes after injection

Method of measurement

automatic brachial pressure gauge device

3

Description

Heart rate per minute

Timepoint

10 minutes before injection, immediately after injection,
10 minutes after injection, 20 minutes after injection

Method of measurement

Finger pulse oximeter

4

Description

Peripheral blood oxygen saturation percentage

Timepoint

10 minutes before injection, immediately after injection,
10 minutes after injection, 20 minutes after injection

Method of measurement

Finger pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Block injection in mandible with 1/8
milliliter of lidocaine 2% solution with epinephrine 1:
80,000 (Darou Pakhsh/iran)

Category

Treatment - Other

2

Description

Intervention group: infiltration injection in maxilla with
1/8 milliliter of lidocaine 2% solution with epinephrine 1:
80,000 (Darou Pakhsh/iran)

Category

Treatment - Other

3

Description

Intervention group: Block injection in mandible with 1/8
milliliter of prilocaine Hcl 3% solution with felypressin
0.03 IU (Darou Pakhsh/iran)

Category

Treatment - Other

4

Description

Intervention group: infiltration injection in maxilla with
1/8 milliliter of prilocaine Hcl 3% solution with felypressin
0.03 IU (Darou Pakhsh/iran)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Restorative, School of Dentistry,
Kermanshah University of Medical Sciences.

Full name of responsible person

Dr Roohollah Sharifi

Street address

Shariati st

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Province

Kermanshah

Postal code

6713954658

Phone

+98 83 3727 7030

Email

roholahsharifi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid najafi

Street address

Building No.2, Shahid Beheshti Boulverd, Vice
Chancellor for Research, Kermanshah University of
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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Zahra lami

Position

Dental student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

Opposite of the post office, Shora st, Dr Shariati st, Kermanshah

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zahra.lami@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Roohollah Sharifi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Email

roholahsharifi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Zahra lami

Position

Dental student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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zahra.lami@yahoo.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

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

The comparative evaluation of maxillary infiltration and mandibular block injection effect on the cardiovascular parameters with 2 different local anesthesia solutions, Lidocaine and prilocaine in Patients Requiring Restorative Treatment of molar Teeth

When the data will become available and for how long

The start of the access period is 6 months after the results are printed

To whom data/document is available

Study data will be available to researchers working in

academic and scientific institutions

Under which criteria data/document could be used

Access to study data is allowed

From where data/document is obtainable

Dr Roohollah Sharifi, Faculty Member of Kermanshah University of Medical Sciences Mobile phone: 09122177490

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

The data can be submitted to Dr. Rouhollah Sharifi by sending an email. r.sharifi@kums.ac.ir

Comments