Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Nov 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 Medial Sciences.
Full name of responsible person
Dr Roohollah Sharifi
Street address
Shariati st
City
Kermanshah
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, Kermafnshah University of Medical Sciences
City
Kermanshah
Province
Kermanshah
Postal code

67146673159

Phone
+98 83 3838 4185

Email
fnajafi@kums.ac.ir

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

City
Kermanshah

Province
Kermanshah

Postal code
6713954658

Phone
+98 83 3722 2400

Email
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

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

City
Kermanshah

Province
Kermanshah

Postal code
6713954658

Phone
+98 83 3722 7151

Fax
+98 83 3722 2400

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

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

City
Kermanshah

Province
Kermanshah

Postal code
6713954658

Phone
+98 83 3722 2400

Email
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