Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Comparative evaluation of cardiovascular effects of 0.5% Ropivacaine front 2% Lidocaine with 1:80000 epinephrine in implant surgery, A double-blind crossover clinical trial

Protocol summary

Study aim

Choosing the appropriate anesthetic drug with the least adverse systemic effects.

Design

This study is a double-blind, crossover randomized clinical trial, in phase 2 as a clinical trial, which performs on 18 patients.In each patient, on one side 2% lidocaine with epinephrine 1/800000 and on the other side 0.5% ropevacaine will be injected. Simple randomization by dropping the coin will be performed to determine the type of anesthetic drug, as well as the surgical site in the first session.

Settings and conduct

This study will be performed in the periodontics department of Shahid Beheshti Dental School. 3.6 ml of each anesthetic drug will be injected in each area with the same technique, in the mandible as buccal and lingual infiltration, and in the maxilla as buccal infiltration and greater palatine block. Patient and surgeon are unaware of the type of drug.

Participants/Inclusion and exclusion criteria

Systemically healthy individuals who need to recieve one implant bilaterally in the molars or premolars area in one jaw are selected. Areas in which bone augmentation, sinus lift surgery and immediate implant placement is needed are excluded.

Intervention groups

Patients who need to recieve 1 implant in the posterior areas in one jaw (left and right) are included in the study. On one side, 0.5% ropevacaine is injected and on the other side, with a 2 weeks interval, 2% lidocaine with 1/800000 epinephrine is injected.

Main outcome variables

Heart rate; systolic and diastolic blood pressure; Saturation of Peripheral Oxygen.; the onset of anesthesia; duration of action; pain during injection and during surgery; duration of postoperative analgesia; analgesic consumption after the surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211127053190N1**
Registration date: **2021-12-01, 1400/09/10**
Registration timing: **prospective**

Last update: **2021-12-01, 1400/09/10**
Update count: **0**

Registration date

2021-12-01, 1400/09/10

Registrant information

Name

Negar Daneshvar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4485 9563

Email address

dr.negardaneshvar@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-13, 1400/09/22

Expected recruitment end date

2022-06-12, 1401/03/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative evaluation of cardiovascular effects of 0.5% Ropivacaine front 2% Lidocaine with 1:80000 epinephrine in implant surgery, A double-blind crossover clinical trial

Public title
Comparison of cardiovascular effects of ropevacaine and lidocaine with epinephrine in implant surgery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who need to place 1 implant bilaterally in the posterior areas (premolar or molar) in one jaw Systemically healthy individuals (ASA I)

Exclusion criteria:
Patients with a history of allergy to local anesthetic agents, amides and sulfides Patients with acute or chronic infection near the surgical site Smokers Alcohol consumption Consumers of antipsychotic drugs, antidepressants and oral contraceptives People who have taken painkillers in the 48 hours before surgery People with a history of chronic facial pain Pregnant and lactating women Patients who need immediate implant placement (class1) Patients who need open / closed sinus lift surgery at the surgical site Patients who need bone augmentation (GBR) at the surgical site Patients who refuse to take part in the research

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **18**
More than 1 sample in each individual
Number of samples in each individual: **2**
The surgical procedure involves injecting lidocaine on one side of the jaw and ropivacaine on the other side

Randomization (investigator's opinion)
Randomized

Randomization description
After the patient's eligibility is determined, the procedure will be explained to the patient and moral satisfaction will be obtained. A simple randomization method is used. The surgical site as well as the type of local anesthesia in the first session are both determined by dropping the coin by the assistant. Both sides (left and right) in a jaw will recieve 1 implant with the same surgical procedure without bone augmentation. Two weeks later, surgery will be performed on the other side with the other anesthetic drug.

Blinding (investigator's opinion)
Double blinded

Blinding description
After determining the type of anesthesia for the first session by dropping the coin, the assistant draws up the drug into the insulin syringes, and delivers it to the surgeon. The assistant will be the only aware person of the type of drug and has no role in further procedures. Both anesthetic drugs are colorlessness and clear, so the insulin syringes will not be covered. After completing the injection and starting the surgery, the parameters are recorded by the surgeon. Both the patient and the surgeon are unaware of the type of local anesthesia.

Placebo
Not used

Assignment
Parallel

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 School of Dentistry, Daneshjou Blvd, Evin, Tehran

City
Tehran

Province
Tehran

Postal code
1983963113

Approval date
2020-08-25, 1399/06/04

Ethics committee reference number
IR.SBMU.DRC.REC.1399.018

Health conditions studied

1

Description of health condition studied
Hemodynamic effects

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Heart rate

Timepoint

Before the injection, immediately after the injection, 10 minutes after the injection, 20 minutes after the injection, 30 minutes after the injection, 1 hour after the injection

Method of measurement

Pulse Oximeter

2

Description

Systolic blood pressure

Timepoint

Before the injection, immediately after the injection, 10 minutes after the injection, 20 minutes after the injection, 30 minutes after the injection, 1 hour after the injection

Method of measurement

Wrist Blood Pressure Monitor

3

Description

Diastolic blood pressure

Timepoint

Before the injection, immediately after the injection, 10 minutes after the injection, 20 minutes after the injection, 30 minutes after the injection, 1 hour after the injection

Method of measurement

Wrist Blood Pressure Monitor

4

Description

Saturation of Peripheral Oxygen (SPo2)

Timepoint

Before the injection, immediately after the injection, 10 minutes after the injection, 20 minutes after the injection, 30 minutes after the injection, 1 hour after the injection

Method of measurement

Pulse Oximeter

5

Description

Onset of anesthesia

Timepoint

From the time when the needle is pulled out of the tissue

Method of measurement

Stopwatch

6

Description

Duration of anesthesia

Timepoint

From the time when the needle is pulled out of the tissue until the anesthetic effect wears off

Method of measurement

Stopwatch

7

Description

The amount of pain felt during the injection

Timepoint

During the injection

Method of measurement

Visual Analogue Scale

8

Description

The amount of pain felt during the surgery

Timepoint

During the surgery

Method of measurement

Visual Analogue Scale

9

Description

Duration of analgesia after the surgery

Timepoint

From the time when the needle is pulled out of the tissue until the time of the onset of pain after the surgery

Method of measurement

Stopwatch

10

Description

Numbers of painkillers taken after the surgery

Timepoint

After the end of the surgery to 1 week

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 3.6 millilitre of the anaesthetic solution is drawn with insulin syringes from 10 millilitre vial of 0.5% ropivacaine made by Molteni Pharmaceutical Company. The injection technique in lower jaw is buccal and lingual infiltration (1 millilitre and 1 millilitre), and in upper jaw is buccal infiltration and greater palatine block (1.5 millilitre and 0.5 millilitre). Then performing the surgical steps of placing a dental implant begins.

Category

Prevention

2

Description

Control group: 3.6 millilitre of the anaesthetic solution is drawn with insulin syringes from 1.8 millilitre carpules of 2% lidocaine with epinephrine 1/80000 made by Darou

Pakhsh Pharmaceutical Company. The injection technique in lower jaw is buccal and lingual infiltration (1 millilitre and 1 millilitre), and in upper jaw is buccal infiltration and greater palatine block (1.5 millilitre and 0.5 millilitre). Then performing the surgical steps of placing a dental implant begins.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid beheshti dental school

Full name of responsible person
Negar Daneshvar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

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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
Negar Daneshvar

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Negar Daneshvar

Position
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Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Person responsible for updating data

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