Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing anesthetic efficacy of 4% Articaine and 2% Lidocaine as buccal infiltration in mandibular ramus block harvesting for bone augmentation in implant patients requirin bone augmentation

Protocol summary

Study aim

The purpose of this study is to investigate the possibility of anesthetizing the target tissues during bone removal surgery from the ramus of the mandible, using the buccal infiltration technique instead of block injection.

Design

Controlled, parallel-group, double-blind and randomized phase 3 clinical trial on 20 patients. The rand function of Excel software is used for randomization.

Settings and conduct

The study is carried out in the surgical department of Qazvin Dental Faculty. After the examination and diagnosis of the need for bone grafting before the implant, the patients enter the study voluntarily. Before the surgery, 2% chlorhexidine mouthwash is swirled in the mouth for 30 seconds and then, one of the two types of anesthesia according to the sealed envelope that has been prepared in advance, is given to the surgeon to inject. Patients and researchers are not aware of the type of anesthesia. The surgeon is one of the researchers and isn't aware of the type of anesthesia.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-65 years old Systemically healthy people capable of filling out questionnaires Exclusion criteria: Patient withdrawal/reluctance to participate in the study

Intervention groups

The intervention group includes patients who are candidates for graft surgery, and 2% lidocaine will be used for anesthesia. The comparison group includes patients who are candidates for graft surgery, and 4% articaine will be used for anesthesia.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230210057378N1**
Registration date: **2023-03-18, 1401/12/27**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-18, 1401/12/27**
Update count: **0**

Registration date

2023-03-18, 1401/12/27

Registrant information

Name

Amir Hasanpour

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-11, 1401/12/20

Expected recruitment end date

2023-07-21, 1402/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing anesthetic efficacy of 4% Articaine and 2% Lidocaine as buccal infiltration in mandibular ramus block harvesting for bone augmentation in implant patients requirin bone augmentation

Public title

Comparing anesthetic efficacy of 4% Articaine and 2% Lidocaine in mandibular bone grafts

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People between 18 and 65 years old Systemically healthy people Having the ability to fill out questionnaires People with bone defects in the edentulous area and candidate for bone graft People who need implants in the upper jaw or the opposite side of the bone removal area in the lower jaw (contralateral)

Exclusion criteria:

Presence of an abscess or any pathological lesion at the injection site History of diabetes, cardiovascular diseases, hypertension and kidney diseases History of allergy to Lidocaine or Articaine local anesthetics Consumption of alcohol or any pain reliever Mentally unable to give informed consent pregnancy and breastfeeding

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be divided into two groups of 4% Artecaine and 2% Lidocaine in the form of blocked randomization. Blocking and sequencing of samples will be done with random allocation software. In order to conceal the random allocation process, the names of the groups are placed in envelopes, numbered on these envelopes from 1 to ... and arranged in a box in order. The researcher who performs the random allocation will not be aware of the contents of the envelopes. The contents of the envelopes indicate the study groups (intervention or placebo) and after ensuring that the sample enters the research and obtaining written consent, the first envelope is taken in order of number and according to the contents of the envelope in are included in one of the study groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be done in a double-blind manner. In this way, the examined patients and the observer will be unaware of the type of intervention. Patients will be given a full explanation of the intervention to be performed with details, but the type of local anesthetic used will remain hidden from them. The type of local anesthetic is determined according to the sealed letter that has been prepared in advance, but the therapist, who is also a researcher, is unaware of the type of local anesthetic and will only know whether it is group one or two. Grouping is done randomly as described above. Cartridges containing anesthetic solutions, with the type of solution and its specifications written on it, are covered with a opaque cover so that only their expiration date is known. On the opaque cover, the anesthetic group (one or two) is written.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Bahonar Blvd

City

Qazvin

Province

Qazvin

Postal code

3419759811

Approval date

2023-03-18, 1401/12/27

Ethics committee reference number

IR.QUMS.REC.1401.360

Health conditions studied

1

Description of health condition studied

Severe bone defects in the jaws

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of people who have pain during surgery

Timepoint
The presence of pain during surgery and throughout its duration
Method of measurement
Asking the patient about the presence or absence of pain

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Lidocaine local anesthetic 2% - Persocaine-E (lidocaine) 2% manufactured by Daroopakhsh company - each cartridge contains 1.8 ml anesthetic solution - 12.5 micrograms epinephrine - 38 mg lidocaine hydrochloride. For each patient, an anesthetic cartridge is injected in the posterior buccal of the mandible in the form of infiltration.
Category
Treatment - Drugs

2

Description
Intervention group: Articaine local anesthetic 4%- Artheek 4% manufactured by New Stetic Company - each cartridge contains 1.8 ml anesthetic solution - 18 micrograms of epinephrine - 72 mg of articaine hydrochloride. For each patient, an anesthetic cartridge is injected in the posterior buccal of the mandible in the form of infiltration.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Qazvin university of medical sciences
Full name of responsible person
Amir Hasanpour
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Sponsors / Funding sources

1

Sponsor
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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
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Amir Hasanpour
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person

Amir Hasanpour

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Student

Latest degree

A Level or less

Other areas of specialty/work

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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 potential data will be shared after de-identifying individuals.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

All people, including researchers working in academic and scientific institutions and those working in the industry

Under which criteria data/document could be used

The data/documentation can be used for scientific purposes, for use in other articles, and for dentists to increase their clinical knowledge.

From where data/document is obtainable

To receive information about the data, please email Mr. Amir Hasanpour as the responsible researcher. E-mail address: ahasanpour23@gmail.com

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

Send an email to the address listed above

Comments