

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparidon of the effectiveness of 4% articaine and 3% mepivacaine on lingual anesthesia by infiltration injection

Protocol summary

Study aim

Comparison of efficacy of infiltration injection of 4% Articaine with 3% Mepivacaine on lingual anasthesia in anterior of mandible

Design

The research is based on the design of a split mouth randomized single_blind clinical trial. The clinical trial has a control group, with parallel groups, single_blind, approved, phase 3 on 20 patients. Left and right were injected in a every other one method.

Settings and conduct

4% Articaine with 1:100000 epinephrine and 3% Mepivacaine are both make by Exir factory, 5 minutes after the anesthetic is injecting, decollation of lingual region is doing for comparising lingual anesthesia and pain recorded in VAS system . The study is performing in the surgery department of the School of Dentistry of the Islamic Azad University

Participants/Inclusion and exclusion criteria

Inclusion criteria: People older than 18 years; patient consent; bilateral mandibular anterior extraction indicated for infiltration injection on both sides of the mandible. Exclusion criteria: Systemic and neurological diseases; Allergy to sulfite (allergic asthma) or local anesthetic; Smoking; alcohol or drug use; Any acute infection and swelling.

Intervention groups

Intervention group 1: one side of anterior of mandible that receives articaine anesthesia Intervention. group 2: The other side of the anterior of mandible that receives mepivacaine anesthesia

Main outcome variables

The amount of pain in the anterior lingual region of the mandible while decollation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170307032929N4**

Registration date: **2021-02-16, 1399/11/28**

Registration timing: **prospective**

Last update: **2021-02-16, 1399/11/28**

Update count: **0**

Registration date

2021-02-16, 1399/11/28

Registrant information

Name

Fina Navi

Name of organization / entity

Islamic Azad University Tehran Dental Branch

Country

Iran (Islamic Republic of)

Phone

+98 912 201 5179

Email address

f_navi@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-23, 1399/12/05

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparidon of the effectiveness of 4% articaine and 3% mepivacaine on lingual anesthesia by infiltration injection

Public title

Comparidon of the effectiveness of articaïne and mepivacaine on lingual anesthesia by infiltration injection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People older than 18 years Complete patient consent to participate in the study. Those in whom upper posterior teeth is bilaterally indicated. Indication of PSA block injection on both sides of the maxilla

Exclusion criteria:

Systemic and neurological diseases. Allergy to sulfite (allergic asthma) or local anesthetic. Smoking, alcohol, drugs. Any acute infection and swelling

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

Mandibular anterior teeth on both sides of jaw

Randomization (investigator's opinion)

Randomized

Randomization description

The mandibular quadrants is dividing into case and control groups, and one of the two test solutions is randomly injecting on each side of the mandible. In each sample, articaïne and mepivacaine is injecting one by one to the left and right, so that if you inject articaïne to the left in the first patient, we inject articaïne to the right in the second patient.

Blinding (investigator's opinion)

Single blinded

Blinding description

The surgeon, examiner, and patient are unaware of any type of injection but the injector is aware, blinding is done by lottery.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Tehran Dental Branch

Street address

9th Neystan, Pasdaran Street

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2020-11-04, 1399/08/14

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.200

Health conditions studied

1

Description of health condition studied

Extraction of anterior teeth of mandibular

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Lingual anesthesia

Timepoint

Immediately after infiltration

Method of measurement

After infiltration injection, with decollation of lingual region the pain is recorded in VAS system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: a part of the anterior of the mandible that receives 4% articaïne anesthesia with epinephrine 1: 100000 and is produced by the elixir factory by infiltration method during the session.

Category

Treatment - Surgery

2

Description

Intervention group: a part of the anterior of the mandible that receives 3% Mepivacaine anesthesia with epinephrine 1: 100000 and is produced by the exir factory by infiltration method during the session.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Islamic Azad University of Medical Sciences
Dental Branch Faculty of dentistry-Department of

Full name of responsible person

Ehsan Daneshmandi

Street address

No. 4, paydarfard street, Araghi St., Tehran

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3149648599

Phone

+98 21 2631 6247

Email

www.ehda72@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Islamic Azad University,
Tehran Dental Branch

Full name of responsible person

Arash Azizi

Street address

No. 9, Pasdaran St., 9th Neyestan, Tehran Town

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drarashazizi@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Tehran islamic Azad university of medical sciences
dental branch

Proportion provided by this source

100

Public or private sector

Private

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**

Islamic Azad University

Full name of responsible person

Fina Navi

Position

Oral And Maxillofacial Surgeon

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Islamic Azad University

Full name of responsible person

Ehsan Daneshmandi

Position

Dentistry Student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

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Latest degree

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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

Participants' data file, consent form (after ensuring that individuals are not identified), number one and two information form, research method, statistical analysis and related tables will be shared

When the data will become available and for how long

Access starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions will also be available, as well as people working in industry

Under which criteria data/document could be used

Access to information forms is only possible for researchers in this field

From where data/document is obtainable

Researcher Mr. Ehsan Daneshmandi contact number:9124128581 Adress:No.4, paydarfard street, Araghi street, tehran Email:www.ehda72@gmail.com

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

Request via Email to be reviewed and the result will be communicated to them within a maximum of one week

Comments