Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effectiveness of 2 substances 4% articaine and 3% mepivacaine on palatal Anesthesia by posterior superior alveolar nerve block on posterior of maxilla

Protocol summary

Study aim
Comparison of efficacy of PSA injection of 4% Articaine with 3% Mepivacaine on palatal anasthesia in posterior of maxilla

Design
The research is based on the design of a split mouth randomized single-blind clinical trial

Settings and conduct
4% Articaine with 1:100000 epinephrine and 3% Mepivacaine are both made by Elixir factory, 5 minutes after the anesthetic was injected, greater palatine injection done for comparising palatal anesthesia and pain recorded in VAS system

Participants/Inclusion and exclusion criteria
People between the ages of 18-35. Complete patient consent to participate in the study Those who have bilateral mandibular third molar surgery are indicated for block injection on both sides of the mandible. No entry conditions: Systemic and neurological diseases. Allergy to sulfite (allergic asthma) or local anesthetic. Smoking, alcohol, drugs. Any acute infection and swelling

Intervention groups
Intervention group 1: A posterior of maxilla side that receives articaine anesthesia Intervention group 2: The other side of the posterior of maxilla that receives mepivacaine anesthesia

Main outcome variables
Comparison of articaine with mepivacaine in PSA nerve block in extraction of posterior teeth of maxilla

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170307032929N5**
Registration date: **2021-02-23, 1399/12/05**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-23, 1399/12/05**
Update count: **0**

Registration date
2021-02-23, 1399/12/05

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
2021-04-19, 1400/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of 2 substances 4% articaine and 3% mepivacaine on palatal Anesthesia by posterior superior alveolar nerve block on posterior of maxilla

Public title
Comparison of the effectiveness of 2 substances articaine and mepivacaine on palatal Anesthesia by posterior superior alveolar nerve block on posterior of maxilla
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People older than 18 years old 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
N/A
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**
Maxilla posterior teeth on both side of the jaw
Randomization (investigator's opinion)
Randomized
Randomization description
The maxillary quadrants were divided into case and control groups, and one of the two test solutions was randomly injected into each individual during one or two visits on each side of the maxilla. In each sample, articaine and mepivacaine were injected one by one to the left and right, so that if you injected articaine to the left in the first patient, we injected articaine to the right in the second patient.
Blinding (investigator's opinion)
Single blinded
Blinding description
The study was performed on 20 eligible individuals who participated in the study with complete satisfaction. They were informed that two approved anesthetics would be used in their surgery. The surgeon, examiner, and patient were unaware of any type of injection but the injector was aware, Pain during greater palatine injection from the patient is recorded by the researcher in the form related to the patient code
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad Univercity Tehran dental Branch
Street address
10th Neistan, 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.1399.202

Health conditions studied

1

Description of health condition studied
Removal of posterior maxillary teeth
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Palatal Anesthesia
Timepoint
5 minutes after PSA block injection
Method of measurement
After 5 minutes with greater palatine injection, the paine has been recorded in VAS system

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:a part of the posterior of the maxilla that receives 4% articaine anesthesia with epinephrine 1: 100000 and is produced by the elixir factory by PSA nerve block method during the session.
Category
Treatment - Surgery

2

Description
Intervention group: a part of the posterior of the maxilla that receives 3% Mepivacaine anesthesia with epinephrine 1: 100000 and is produced by the elixir factory by PSA nerve block 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
Zeinab Boushehrian

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
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drarashazizi@yahoo.com

Web page address

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
Medical doctor

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Name of organization / entity
Islamic Azad University

Full name of responsible person
Zeinab Boushehrian

Position
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Latest degree
A Level or less

Other areas of specialty/work
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Person responsible for updating data

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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

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 Ms. Zeinab Boushehrian contact Number:+989128147941 Adress:No. 4, paydarfard street, Araghi street, tehran Emal: www.z.nagisa@gmail.com

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

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

Comments