

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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

Registration timing: **registered_while_recruiting**

Study aim

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

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

Update count: **0**

Registration date

2021-02-23, 1399/12/05

Design

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

Registrant information

Name

Fina Navi

Name of organization / entity

Islamic Azad University Tehran Dental Branch

Country

Iran (Islamic Republic of)

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Email address

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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 comparing palatal anesthesia and pain recorded in VAS system

Recruitment status

Recruitment complete

Funding source

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

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

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

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

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**

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 University 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 pain 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Arash Azizi

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Phone

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Email

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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

Contact

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

Contact

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Full name of responsible person

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Position

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Latest degree

A Level or less

Other areas of specialty/work

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Email

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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 Address: No. 4, paydarfard street, Araghi street, tehran Email:
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