

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparative evaluation of anesthetics efficiency of 1.8 ml: inferior alveolar nerve block with Lidocaine, mental nerve block with Articaine, infiltration with Articaine, in irreversible pulpitis of mandibular canines

Protocol summary

Study aim

Determine success rate of anesthetics efficiency of 1.8 ml: inferior alveolar nerve block with Lidocaine, mental nerve block with Articaine, infiltration with Articaine, in irreversible pulpitis of mandibular canines

Design

Randomized, parallel group trial with blinded outcome assessment. Randomisation will be written on pieces of paper and kept in sealed envelopes.

Settings and conduct

The study will be performed by 2 dentists in a private clinic in Rafsanjan. After the anesthesia injection, patients and the operator are unaware (double-blind). patients are instructed to report any pain at any stage of treatment in Visual Analogue Scale (VAS) form.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy adult patients 18 to 60 years old having mandibular canine with symptomatic irreversible pulpitis and normal periapical radiograph appearance Exclusion criteria: Increasing the width of the periodontal ligament or radiolucency in radiography; canine teeth sensitive to pressure; sensitivity to articaine 4% or lidocaine 2% or epinephrine; American Society of Anesthesiologists (ASA) III, IV patients; pregnancy or breastfeeding; Addicted patients

Intervention groups

In the first group, infraalveolar nerve block with 1.8 ml of 2% lidocaine solution, the second group with mental nerve block with 1.8 ml of 4% articaine solution, and the third group with mandibular canine infiltration with 1.8 ml of 4% articaine solution. 10 minutes after the anesthetic injection, the patient is asked about the numbness of the lower lip, and if the answer is negative, he is excluded from the study, and if the answer is positive, the tooth will be isolate by a rubberdam, the caries will be removed. The access cavity is prepared and instrumentation will be performed.

Main outcome variables

Pain rate by Visual Analogue Scale form

General information

Reason for update

Acronym

IANB,MINB,ASA,IP,PDL

IRCT registration information

IRCT registration number: **IRCT20210515051306N4**

Registration date: **2023-07-19, 1402/04/28**

Registration timing: **prospective**

Last update: **2023-07-19, 1402/04/28**

Update count: **0**

Registration date

2023-07-19, 1402/04/28

Registrant information

Name

Ramin Abazarpoor

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-01, 1402/05/10

Expected recruitment end date

2023-09-05, 1402/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of anesthetics efficiency of 1.8 ml: inferior alveolar nerve block with Lidocaine, mental nerve block with Articaine, infiltration with Articaine, in irreversible pulpitis of mandibular canines

Public title

Anesthetics efficiency of 1.8 ml: inferior alveolar nerve block with Lidocaine, mental nerve block with Articaine, infiltration with Articaine, in irreversible pulpitis of mandibular canines

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy adult patients 18 to 60 years old Having a mandibular canine tooth with symptomatic irreversible pulpitis Normal periapical radiographic appearance

Exclusion criteria:

Patients under age of 18 and over the age of 60 years American Society of Anesthesiologists (ASA) III,IV patients Pregnancy or breastfeeding Any type of medication that could potentially interact with the anesthetic solution Spontaneous pain Periodontal disease or unable to get restoration Having pain killer late 12 hours History of sensitivity to 4% articaine, 2% lidocaine or epinephrine Widening PDL Radiolucency in radiography Canine teeth sensitive to percussion Addicted

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **165**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization individually 3 categories (inferior alveolar nerve block with 1.8 ml Lidocaine, mental nerve block with 1.8 ml Articaine, infiltration with 1.8 ml Articaine) were written on 165 pieces of paper and kept in sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

The papers are placed in the envelope and before each injection, another dentist colleague takes them out by chance, and written injection is done by him so that the operator and patient are not aware of the type of anesthesia technique.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Rafsanjan University of Medical Sciences

Street address

Central Organization, Imam Ali Blvd

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Rafsanjan

Province

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7717933777

Approval date

2023-06-14, 1402/03/24

Ethics committee reference number

IR.RUMS.REC.1402.038

Health conditions studied**1****Description of health condition studied**

Irreversible pulpitis of the mandibular canines

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes**1****Description**

Pain score during treatment on Visual Analogue Scale (VAS)

Timepoint

Before administration of the anesthetic solution and during root canal treatment

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: First intervention group: In the first group, infraalveolar nerve block is injected with 1.8 ml of 2% lidocaine solution with 1.100000 epinephrine, using the methods mentioned in Malamed. 10 minutes after the anesthetic injection, the patient is asked about the numbness of the lower lip, and if the answer is negative, he is excluded from the study, and if the answer is positive, the tooth is isolated by a rubber band, and the caries is removed. The access hole is prepared and root canal preparation is done. Patients are taught to report any pain during each stage of the preparation of the access hole and the entry of the instrument into the canal and cleaning to be recorded in the VAS form.

Category

Treatment - Drugs

2

Description

Intervention group: Second intervention group: The second group of mental nerve block is injected with 1.8 ml of 4% articaine solution with 1.100000 epinephrine, using the methods mentioned in Malamed. 10 minutes after the anesthetic injection, the patient is asked about the numbness of the lower lip, and if the answer is negative, he is excluded from the study, and if the answer is positive, the tooth is isolated by a rubber band, and the caries is removed. The access hole is prepared and root canal preparation is done. Patients are taught to report any pain during each stage of the preparation of the access hole and the entry of the instrument into the canal and cleaning to be recorded in the VAS form.

Category

Treatment - Drugs

3

Description

Intervention group: The third intervention group: The third group is infiltration with 1.8 ml of articaine 4% solution with 1.100000 epinephrine, using the methods mentioned in Malamed. 10 minutes after the anesthetic injection, the patient is asked about the numbness of the lower lip, and if the answer is negative, he is excluded from the study, and if the answer is positive, the tooth is isolated by a rubber band, and the caries is removed. The access hole is prepared and root canal preparation is done. Patients are taught to report any pain during each stage of the preparation of the access hole and the entry of the instrument into the canal and cleaning to be recorded in the VAS form.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Private Clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

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Position

Assistant professor

Latest degree

Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available