Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the success rate of infiltrating anesthetic injection of 1.8 ml of Articaine, injection of 1.8 ml of Articaine as mental block and injection of 1.8 ml of Lidocaine as mental block in mandibular incisor teeth with irreversible pulpitis: A randomized clinical trial

Protocol summary

Study aim
Determine success rate of infiltrating anesthetic injection of 1.8 ml of Articaine, injection of 1.8 ml of Articaine as mental block and injection of 1.8 ml of Lidocaine as mental block in mandibular incisor teeth with irreversible pulpitis

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 citeria: 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, infiltrating of 1.8 ml of 4% Articaine solution, the second group of 1.8 ml of 4% Articaine solution as mental block and the third group of 1.8 ml of 2% Lidocaine solution as mental block . 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
MINB,IP,PDL

IRCT registration information
IRCT registration number: **IRCT20210515051306N3**
Registration date: **2023-07-16, 1402/04/25**
Registration timing: **prospective**

Last update: **2023-07-16, 1402/04/25**
Update count: **0**

Registration date
2023-07-16, 1402/04/25

Registrant information

Name
Ramin Abazarpoor

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 34 3424 2322

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abazarpoor@rums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-06, 1402/05/15

Expected recruitment end date

2023-09-06, 1402/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the success rate of infiltrating anesthetic injection of 1.8 ml of Articaine, injection of 1.8 ml of Articaine as mental block and injection of 1.8 ml of Lidocaine as mental block in mandibular incisor teeth with irreversible pulpitis: A randomized clinical trial

Public title

The success rate of infiltrating anesthetic injection of 1.8 ml of Articaine, injection of 1.8 ml of Articaine as mental block and injection of 1.8 ml of Lidocaine as mental block in mandibular incisor teeth with irreversible pulpitis: A randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy adult patients 18_60 years old Having a mandibular incisor 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 breasfeeding 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 sensititivity to 4% articaine, 2% lidocaine or epinephrine Widening PDL Radiolucency in radiography Incisor 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 (Infiltrating anesthetic injection of 1.8 ml of Articaine, injection of 1.8 ml of Articaine as mental block and injection of 1.8 ml of Lidocaine as mental block) 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

Imam Ali Blvd , Centeral Organization

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2023-06-24, 1402/04/03

Ethics committee reference number

IR.RUMS.REC.1402.041

Health conditions studied

1

Description of health condition studied

Irreversible pulpitis of the mandibular incisor

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: The first group of infiltrating anesthetic injection of 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

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 of mental 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

Recruitment centers

1

Recruitment center

Name of recruitment center
Private Clinic

Full name of responsible person
Ramin Abazarpoor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences

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?
No

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
Ramin Abazarpoor

Full name of responsible person
Rafsanjan University of Medical Sciences

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
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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