

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Primary and Supplementary Anesthetic Efficacy of Modified Infiltration Technique with 4% Articaine versus Inferior Alveolar Nerve Block with 2% lidocaine in Mandibular molars with Irreversible Pulpitis: A Randomized Clinical Trial

Protocol summary

Study aim

To study the efficacy of primary and supplementary injection with modified infiltration technique using Articaine 4% in mandibular molars diagnosed with irreversible pulpitis, and to compare it with inferior alveolar nerve block using lidocaine 2%.

Design

A concealed, randomized, parallel-designed, phase III clinical trial on 108 patients in three groups.

Settings and conduct

This study will be done in the Endodontic Department and subordinate clinics, School of Dentistry, Shahid Beheshti University of Medical Sciences, Tehran, Iran. The statistician will be blinded to the aims and methods of the injection. Also, the investigator will be unaware of the randomization table, and the allocated injection for each patient. The nurse and the practitioner will not be involved in any other steps of this study.

Participants/Inclusion and exclusion criteria

Healthy patients with an age between 18 and 65, and with a first or second mandibular molar diagnosed with irreversible pulpitis will include in this study. Pregnant or nursing females will be excluded from this study.

Intervention groups

In the primary modified infiltration technique group, a two-step subperiosteal injection using articaine 4% with 1:100.000 epinephrine, will be performed in the middle point of the line between the most apical part of the buccal scalloped gingiva of the target tooth and its nearby tooth. This injection will be performed twice; first, distally, and second, mesially. In the Inferior alveolar nerve block group, a conventional Inferior alveolar nerve (IANB) block will be performed, using lidocaine 2% with 1:100.000 epinephrine. In the supplemental group, after using an IANB, another subperiosteal injection will be done.

Main outcome variables

The target tooth's response to electric pulp test. The patient's pain score while injection, access cavity preparation, and initial filing on 170 mm visual analog scale.

General information

Reason for update

Since the subperiosteal nature of the injections cannot be assured, the "Modified infiltration technique" was used instead of the subperiosteal technique.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200301046656N1**

Registration date: **2021-01-21, 1399/11/02**

Registration timing: **prospective**

Last update: **2021-05-06, 1400/02/16**

Update count: **1**

Registration date

2021-01-21, 1399/11/02

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-31, 1399/11/12

Expected recruitment end date

2021-04-09, 1400/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Primary and Supplementary Anesthetic Efficacy of Modified Infiltration Technique with 4% Articaine versus Inferior Alveolar Nerve Block with 2% lidocaine in Mandibular molars with Irreversible Pulpitis: A Randomized Clinical Trial

Public title

Anesthetic Efficacy of Modified Infiltration Technique in mandibular molars

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

having a first/second mandibular molar tooth diagnosed with irreversible pulpitis absence of any systemic disease absence pregnancy or nursing for female participants occurrence of periapical lesion on preoperative radiograph(s) absence of any inflammation or lesion/wound in anesthetic injection's area absence of a history of any allergic reaction to the materials used in the present study

Exclusion criteria:

more than 0.5 mm mobility on occluso-gingival and/or bucco-lingual and/or mesio-distal direction. taking analgesic medications less than a day before the beginning of the treatment absence of vital pulpal tissue upon access cavity preparation

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization table will be provided by the statistician. The permuted block randomization method will be used for randomizing the participants. In each block, randomization sequences will be generated using Microsoft Excel software. The statistician will be blinded to the study's aims and methods of injections.

Blinding (investigator's opinion)

Single blinded

Blinding description

The investigator will leave the treatment room after evaluating the inclusion and exclusion criteria. Then, the practitioner will carry out the injection after opening the allocated opaque and sealed envelope just before the injection. afterward, the practitioner will use a rubber dam to blind the investigator and tell the investigator to come back to the treatment room and collect the required information. The code on the envelopes, that distinguishes the type of injection using the randomization sequence, will be recorded in the patients' profiles. The investigator will be blinded to the type of injection. Due to the different methods of the two injections, completely blinding the practitioner and patients will not be applicable. The statistician will be blinded to the aims and steps of the present study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

the Ethics Committee of Shahid Beheshti University of Medical Sciences

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the Ethics Committee of Shahid Beheshti University of Medical Sciences, Evin, Tehran.

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Approval date

2020-01-28, 1398/11/08

Ethics committee reference number

IR.SBMU.DRC.REC.1398.227

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

Irreversible pulpitis

ICD-10 code

K04.02

ICD-10 code description

Irreversible pulpitis

Primary outcomes

1

Description

Patient's perceived pain score

Timepoint

before the injection, while injecting, access cavity preparation, and initial filing.

Method of measurement

170 mm Heft Parker Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Subperiosteal group. In this group, patients will receive an anesthetic subperiosteal injection of 1.8 mL articaine 4% with 1:100.000 epinephrine with an extra short 27-gauge needle. This injection will be carried out in both the mesial and distal parts.

Category

Treatment - Other

2

Description

Control group: Inferior alveolar nerve block group. In this group, patients will receive an inferior alveolar nerve block with 1.8 mL lidocaine 2% with 1:100.000 epinephrine using a long 27-gauge needle.

Category

Treatment - Other

3

Description

Supplementary modified infiltration technique group: in this group, patients will receive an Inferior alveolar nerve block anesthesia, and after the numbness of the lower lip, they will receive a subperiosteal injection of 1.8 mL 4% articaine with 1:100.000 epinephrine, with a 27-gauge, extra short needle.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry, Shahid Beheshti University of Medical Sciences.

Full name of responsible person

Mandana Naseri Salehabadi

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Sponsors / Funding sources

1

Sponsor

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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
Shahid Beheshti 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available