

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the anesthetic efficacy of articaine 4% as supplemental intraligamentary injection with buccal infiltration in posterior mandibular teeth with irreversible pulpitis

Protocol summary

Study aim

Comparison of the anesthetic efficacy of articaine 4% as supplemental intraligamentary injection with buccal infiltration in posterior mandibular teeth with irreversible pulpitis.

Design

Prospective randomized clinical trial

Settings and conduct

All the patients will receive inferior alveolar nerve block(1.5ml) and long buccal(0.3 ml) injections of lidocaine 2% with epinephrine 1/100000. After 15 minutes the patients without lip numbness will be excluded. The teeth will be examined by cold test and electrical pulp tester and the patients indicate their pain on Heft Parker Visual Analogue Scale. The pulse will be recorded. If the electrical pulp test number will be under 80 we will consider supplemental injection. All the injections will be done by one person. After 5 minutes the teeth will be examined by cold test and electrical pulp tester and the patients will indicate their pain and the pulse will be recorded and the access cavity will be prepared and initial filing will be done. If the patients report moderate to severe pain during these procedures another anesthetic technique will be considered for them and will be reported as a failure

Participants/Inclusion and exclusion criteria

One hundred patients in Endodontic Department, School of Dentistry, Shahid Beheshti University of Medical Sciences. Patients with a first or second vital mandibular molar without spontaneous pain, with positive response to electrical pulp tester and prolonged response to cold test.

Intervention groups

Subgroup 1: 0.4 ml of the supplemental intraligamentary injection with articaine 4% with epinephrine 1/80000.
Subgroup 2: 1.8 ml of the supplemental buccal infiltration injection with articaine 4% with epinephrine 1/80000.

Main outcome variables

The success of the injections was defined as the ability to prepare access cavity and initial filing with no or mild pain (0 or less than 54 mm on HP-VAS).

General information

Reason for update

To enter the actual recruitment start and end date.

Acronym

IRCT registration information

IRCT registration number: **IRCT2015072023253N1**
Registration date: **2016-08-17, 1395/05/27**
Registration timing: **prospective**

Last update: **2020-07-19, 1399/04/29**

Update count: **1**

Registration date

2016-08-17, 1395/05/27

Registrant information

Name

Nazanin Zargar

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-04-08, 1395/01/20

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

2016-10-23, 1395/08/02

Actual recruitment end date

2017-03-18, 1395/12/28

Trial completion date

2017-03-18, 1395/12/28

Scientific title

Comparison of the anesthetic efficacy of articaine 4% as supplemental intraligamentary injection with buccal infiltration in posterior mandibular teeth with irreversible pulpitis

Public title

Comparison of the anesthetic efficacy of articaine 4% in two supplemental anesthetic injections

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients older than 18 without any systemic diseases
First or second mandibular molars with irreversible pulpitis
No periapical lesion in radiography
Prolonged response with moderate to severe pain to cold test and check the vitality by electrical pulp tester
Vital coronal pulp tissue

Exclusion criteria:

Allergy to lidocaine or articaine
Lactate or pregnancy
Using analgesic drugs since 12 hours before the treatment
Mobility more than 0.5mm
Probing more than 3mm
Severe dental pain needs emergency treatment
Teeth with full crowns
No lip numbness after the Inferior Alveolar Nerve Block injection
No pulp exposure after removing caries

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified permutations blocks randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

All injections are done by a single clinician. The principle investigator or outcome assessor is different from the operator who administers anesthesia and root canal therapy. So he is blind to anesthetic technique used. The patients and the clinician who administered anesthesia

are not blind to anesthetic technique. The statistician who analyzed the data was blinded to the procedure.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Dental Research Center, Shahid Beheshti University of Medical Sciences

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School of Dentistry, Shahid Beheshti University of Medical Sciences, Daneshjoo Blvd, Evin Ave, Shahid Chamran Highway, Tehran, Iran

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1983963113

Approval date

2015-11-01, 1394/08/10

Ethics committee reference number

IR.SBMU.RIDS.REC.1394.24

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

Irreversible pulpitis

ICD-10 code

k04.0

ICD-10 code description

Pulpitis

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

Anesthesia

Timepoint

After inferior alveolar nerve block injection, after supplemental injection

Method of measurement

Electrical pulp tester

2**Description**

Pulse

Timepoint

Before inferior alveolar nerve block injection, after inferior alveolar nerve block injection, after supplemental injection

Method of measurement

Pulse-oximetre

3**Description**

Pain during injection

Timepoint

Pain during inferior alveolar nerve block and supplemental injection

Method of measurement

Heft Parker Visual Analogue Scale

4**Description**

Pain

Timepoint

After inferior alveolar nerve block and supplemental injection

Method of measurement

Heft Parker Visual Analogue Scale

Secondary outcomes

empty

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

After inferior alveolar nerve block injection with lidocaine and epinephrine 1/80000, the supplemental buccal infiltration injection with articaine 4% and epinephrine 1/100000 will be done

Category

Treatment - Other

2**Description**

After inferior alveolar nerve block injection with lidocaine and epinephrine 1/80000, the intraligamentary injection with articaine 4% and epinephrine 1/100000 will be done

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Endodontic Department, School of Dentistry, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nazanin Zargar

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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

Shahid Behsehti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nazanin Zargar

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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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