

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The comparison of anesthetic efficacy of Articaine versus Lidocaine in Inferior Alveolar Nerve Block plus Intraligamentary injections in mandibular molar teeth with irreversible pulpitis

Protocol summary

Study aim

The objective of this study was to compare the anesthetic efficacy of supplemental intraligamentary (PDL) injections of 4% articaine with 2% lidocaine in the first and second mandibular molars _diagnosed with irreversible pulpitis_ after an ineffective inferior alveolar nerve block (IANB), using the same anesthetic.

Design

Triple blind, consealed randomised, superiority, parallel group trial .A third phase study.

Settings and conduct

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

Participants/Inclusion and exclusion criteria

Inclusion criteria include:patients who a) have no systemic diseases, b) are 18 years old or older, c) have a first or second vital mandibular molar with no sign of periapical pathosis in radiographs, and d) do not take any pain killers 12 h prior to the treatment.Exclusion criteria comprise a) teeth with more than 0.5 mm mobility and more than 3 mm probing depth in their mesial or distal surfaces, b) teeth with no vital coronal pulp tissue on access, and c) patients with hypersensitivity to lidocaine or articaine, pregnancy or lactation.

Intervention groups

1- Men and woman with a first or second mandibular molar who anesthetize with lidocaine 2-Men and women with a first or second mandibular molar who anesthetize with articaine

Main outcome variables

anesthetic efficacy of supplemental intraligamentary (PDL) injections of 4% articaine with 2% lidocaine in the first and second mandibular molars _diagnosed with irreversible pulpitis_ after an ineffective inferior alveolar nerve block (IANB), using the same anesthetic.

General information

Reason for update

to enter the actual recruitment start and end date

Acronym

IRCT registration information

IRCT registration number: **IRCT2015100523253N2**

Registration date: **2016-10-17, 1395/07/26**

Registration timing: **prospective**

Last update: **2019-12-31, 1398/10/10**

Update count: **1**

Registration date

2016-10-17, 1395/07/26

Registrant information

Name

Nazanin Zargar

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

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
The comparison of anesthetic efficacy of Articaine versus Lidocaine in Inferior Alveolar Nerve Block plus Intraligamentary injections in mandibular molar teeth with irreversible pulpitis

Public title
Comparison of Articaine and Lidocaine as an anesthetic supplemental injection

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients older than 18 without any systemic diseases; First or second mandibular molar with irreversible pulpitis; No periapical lesion in radiography; Response to Electrical Pulp Tester; Prolonged response to the cold test
Exclusion criteria:
Allergic response to Lidocaine or Articaine; pre apical radiolucency; Lactate or pregnant women; Using analgesic drugs since 12 hours before the treatment; Mobility more than 0.5 mm; Probing more than 3 mm in mesial and distal; Severe dental pain that needs emergency treatment; Nonvital coronal pulp tissue; Teeth with full crown; No lip numbness after the Inferior Alveolar Nerve Block injection; No pulp exposure after removing caries

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**
Actual sample size reached: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
All patients are divided into experimental groups using stratified permutations blocks randomization. Patients are stratified to 4 groups according to the gender and the type of the tooth (first or second mandibular molar). Then cases in every subgroup are randomly assigned into 2 groups of lidocaine and articaine with random block size of 4.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Equal numbers of lidocaine and articaine cartridges,

which are covered and given a code, are provided. To obtain allocation concealment, an assigned nurse is aware of the codes and, according to the groups (lidocaine or articaine), gives out the cartridges randomly. There is 1 code for each of the 2 cartridges packed together. One clinician completes the designated questionnaire and another one administers the injections. All the injections are given by the same clinician. Block and supplemental injections are done with the same anesthetic. This is a triple blind study; which means that the clinician who gives the injection, the patients, outcome assessor and the statistician are not aware of the anesthetic.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

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

Street address

Daneshjoo Boulevard, Evin Avenue, Shahid Chamran Highway, Tehran, Iran

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1983963113

Approval date

2015-12-22, 1394/10/01

Ethics committee reference number

IR.SBMU.RIDS.REC.1394.63

Health conditions studied

1

Description of health condition studied

Irreversible pulpitis

ICD-10 code

B95

ICD-10 code description

Streptococcus and staphylococcus as the cause of diseases classified to other chapters

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-oximeter

3

Description

Pain during injection

Timepoint

During Inferior Alveolar Nerve Block and supplemental injection

Method of measurement

Heft Parker Visual Analog Scale

4

Description

Pain

Timepoint

After Inferior Alveolar Nerve Block and supplemental injection

Method of measurement

Heft Parker Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description

After Inferior Alveolar Nerve Block injection with Lidocaine with Epinephrine 1/80000, supplemental Intraligamentary injection with the same anesthetic material will be done.

Category

Treatment - Drugs

2

Description

After Inferior Alveolar Nerve Block injection with Articaine with Epinephrine 1/100000, supplemental Intraligamentary injection with the same anesthetic

material will be done.

Category

Treatment - Drugs

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

Dr.Nazanin Zargar(The assistant professor of Shahid Beheshti Dental School)

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Zarghi

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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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nazanin Zargar

Position

Shahid Beheshti University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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