

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the anesthetic efficacy of Articaine infiltration versus lidocaine inferior alveolar nerve block in pulp therapy of lower second primary molars

Protocol summary

Study aim

Comparison of the effect of articaine infiltrated anesthesia with lidocaine block anesthesia in the treatment of pulpotomy of mandibular second molars

Design

A randomized clinical trial with cross-over groups, double-blind, phase 2-3 on 76 patients

Settings and conduct

In this study, the pain of articaine infiltration and lidocaine infra alveolar nerve block was investigated. Both injections are given to all individuals, the first group's infusion of lidocaine infra alveolar nerve block injection and the second session infusion of articaine infiltration, the first two sessions infusion of articaine infiltration and the second infusion of infra alveolar nerve block infusion of lidocaine to each person using lidocaine. The VAS chart measures the amount of pain before and at the start of the injection. The participant and the VAS reviewer will not be aware of the type of injection.

Participants/Inclusion and exclusion criteria

Healthy children aged four to ten years who need treatment for mandibular pulp on both sides are included in our study. In terms of cooperation in the first session with fluoride therapy and prophylaxis, we place these children in the positive or completely positive category of the Frankel classification, and in the medical history, we check that they have no problem performing anesthesia injections. Children who have any sores or mucosal lesions during treatment sessions at the buccal vestibule or do not return for the second treatment session will be excluded from the study and replaced with another child.

Intervention groups

Group one: The first session of lidocaine infra alveolar nerve block injection and the second session of articaine infiltration injection Group 2: The first session of articaine infiltration injection and the second session of lidocaine infra alveolar nerve block injection

Main outcome variables

Reduce pain during anesthesia injection.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170101031697N5**

Registration date: **2021-01-07, 1399/10/18**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-07, 1399/10/18**

Update count: **0**

Registration date

2021-01-07, 1399/10/18

Registrant information

Name

Afshin Parvizpanah

Name of organization / entity

Hormozgan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-26, 1399/10/06

Expected recruitment end date

2021-01-25, 1399/11/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the anesthetic efficacy of Articaine infiltration versus lidocaine inferior alveolar nerve block in pulp therapy of lower second primary molars

Public title

Comparison of the effect of articaine infiltrated anesthesia with lidocaine block anesthesia in the treatment of mandibular second molar palpotomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy children four to ten years old who need treatment for the pulp molars of the mandible on both sides.

Exclusion criteria:

Children who have any sores or mucosal lesions during treatment sessions in the buccal vestibule.

Age

From **4 years** old to **10 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, randomization of participants as an individual unit and simple randomization, which will be divided into two equal groups based on the random division command in SPSS software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant: The participant's blindness is such that before injecting anesthesia, the person is asked to open his mouth, at which time the injector waits for a minute and then injects. This causes the patient not to notice the injection. Impact Assessor: The outcome assessor will not be aware of the type of injection when evaluating the patient.

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

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

Ethics Committee of Bandar Abbas University of Medical Sciences

Street address

Ethics Committee of Bandar Abbas University of Medical Sciences, Research Deputy Building, Shahid Mohammadi Hospital, Jomhoori Islami Blvd.

City

Bandar Abbas

Province

Hormozgan

Postal code

7916613885

Approval date

2020-12-23, 1399/10/03

Ethics committee reference number

IR.HUMS.REC.1399.462

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

Local anesthesia

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

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

Pain when exposing the pulp

Timepoint

When exposing the pulp

Method of measurement

Using the Visual Analogue Scale chart

2**Description**

Pain during injection start

Timepoint

During injection start

Method of measurement

Using the Visual Analogue Scale chart

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the first session of lidocaine infraalveolar nerve block injection and the second session of articaine infiltration injection. In this group, in order to pulpotomy of second primary mandibular molar in one session, after preparing radiography and performing the initial steps for treatment, infra alveolar nerve block injection using carpol lidocaine 2% with epinephrine 1: 100000, for a child at one minute will be done. After the appropriate time (10 minutes) and ensuring complete anesthesia by using the lip anesthesia index, we begin the process of removing the caries and preparing the access cavity, and the child's reaction will be measured at the moment of pulp exposure. Before the test, we explain the VAS (Visual Analogue Scale) diagram and how to show the amount of discomfort on it to the child and immediately ask the child during the cutting of the cavity in the dentin or in cases of pulp treatment at the moment of pulp exposure to mark the appropriate face on the VAS chart, depending on the amount of pain or discomfort. The same child will be treated for the pulpotomy of second primary mandibular molar in opposite side in the next session, one week after the first session. After preparing the radiography and performing the initial steps for treatment, infiltration injection in the vicinity of the target tooth using carpool articaine 4% with epinephrine 1: 100000, will be performed for the child in one minute. After the appropriate time (10 minutes) and ensuring complete anesthesia by using the lip anesthesia index, we begin the process of caries removal and preparation of the access cavity, and the child's reaction will be measured at the moment of pulp exposure. Explain the Visual Analogue Scale and how to display the amount of discomfort on it to the child and immediately when cutting the cavity in the dentin or in cases of need for pulp treatment at the moment of pulp exposure, we ask the child to mark the appropriate face on the VAS chart, depending on the amount of pain or discomfort.

Category

Treatment - Drugs

2

Description

Intervention group: The first session of articaine infiltration injection and the second session of lidocaine infra alveolar nerve block injection. In this group, in order to pulpotomy of second primary mandibular molar in one session, after preparing radiography and performing the initial steps for treatment, infiltration injection in the vicinity of the target tooth using 4% carpool articaine with 1: 100000 epinephrine, for the child It will be done in one minute. After the appropriate time (10 minutes) and ensuring complete anesthesia by using the lip anesthesia index, we begin the process of removing the caries and preparing the access cavity, and the child's reaction will be measured at the moment of pulp exposure. Before the test, we explain the VAS (Visual Analogue Scale) diagram and how to show the amount of discomfort on it to the child and immediately ask the

child during the cutting of the cavity in the dentin or in cases of pulp treatment at the moment of pulp exposure to mark the appropriate face on the VAS chart, depending on the amount of pain or discomfort, and the same child will be treated for the opposite side of the mandible in the next session, one week after the first session. After preparing radiography and performing the initial steps for treatment, infra alveolar nerve block injection using carpol lidocaine 2% with epinephrine 1: 100000, for a child at one minute will be done. After the appropriate time (10 minutes) and ensuring complete anesthesia by using the lip anesthesia index, we begin the process of removing the caries and preparing the access cavity, and the child's reaction will be measured at the moment of pulp exposure. Before the test, we explain the VAS (Visual Analogue Scale) diagram and how to show the amount of discomfort on it to the child and immediately ask the child during the cutting of the cavity in the dentin or in cases of pulp treatment at the moment of pulp exposure to mark the appropriate face on the VAS chart, depending on the amount of pain or discomfort.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Clinic of Bandar Abbas Faculty of Dentistry

Full name of responsible person

Sara Esmaeili

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Teamour Aghamolai

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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
Bandare-abbas 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
Bandare-abbas University of Medical Sciences

Full name of responsible person
Sara Esmaeili

Position
Pediatric dentist

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Position
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document

The information obtained from this study can be shared without the ability to identify participants.

When the data will become available and for how long

From October 2021

To whom data/document is available

Researchers and referees

Under which criteria data/document could be used

Obtaining a written permit and mentioning the name in the sources and references

From where data/document is obtainable

Sara Bakhshaei saraesmaili43@gmail.com

What processes are involved for a request to access data/document

The request must first be emailed and answered after review and approval.

Comments