

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the anesthetic efficacy of 4% Articaine infiltration versus 2% Lidocaine inferior alveolar nerve block in pulp therapy of mandibular primary second molars in 5-8 years old children

Protocol summary

Study aim

Comparison of the anesthetic efficacy of 4% articaine infiltration versus 2% lidocaine inferior alveolar nerve block in pulp therapy of mandibular primary second molars in 5-8 years old children

Design

Randomized clinical trial with control group, Parallel design, 40 patients. SAS software version 9 was used for randomization.

Settings and conduct

In this study, 40 children aged 5 to 8 years referred to Guilan dental clinic who need pulp therapy for mandibular second molars in both sides, are divided randomly in two A and B groups. Patients in A group receives Articaine 4% infiltration in one side in the first session and Lidocaine 2% Inferior alveolar nerve block in the other side in the second session. Patients in B group receives Lidocaine 2% Inferior alveolar nerve block in one side in the first session and Articaine 4% infiltration in the other side in the second session. In this study patient pain grade is recorded by Facial image scale(FIS) and objective reaction of children by SEM during pulp exposure. All the injections are conducted by a pediatric dentist who is unaware of type of the drug and study design. Anesthetic drugs are situated in the same boxes which are without name and marked by the letters "A" and "B".

Participants/Inclusion and exclusion criteria

Inclusion criteria: children 5-8 years old who need pulp therapy of second primary molar in mandibular Exclusion criteria: Presence of any Allergic reaction to anesthetic soluble

Intervention groups

Intervention group:: patients will receive 1.8 ml Articaine 4% infiltration injection in mandibular primary second molar control group: : patients will receive 1.8 ml Lidocaine 2% Inferior alveolar nerve block injection and

in both groups their tooth anesthesia during the pulp therapy of mandibular primary second molar will be evaluated

Main outcome variables

Facial image scale; sound, eye and body movement scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200622047887N1**

Registration date: **2020-09-06, 1399/06/16**

Registration timing: **retrospective**

Last update: **2020-09-06, 1399/06/16**

Update count: **0**

Registration date

2020-09-06, 1399/06/16

Registrant information

Name

Dariush Dorani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 4469 1467

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-31, 1399/05/10

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the anesthetic efficacy of 4% Articaine infiltration versus 2% Lidocaine inferior alveolar nerve block in pulp therapy of mandibular primary second molars in 5-8 years old children

Public title
Comparison of the anesthetic efficacy of Articaine infiltration versus Lidocaine inferior alveolar nerve block in children pulpotomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
5-8 years healthy children who require pulp therapy of mandibular primary second molar in both sides appropriate cooperation of child for dental treatment under local anesthesia(class of 3 or 4 Frunkle scale) parents' consent for study entrance
Exclusion criteria:
Presence of any inflammation or infection of soft tissue near the injection area Presence of any Allergic reaction to anesthetic soluble Children communication problem with others Presence of a systemic problems that interferes with the use of epinephrine containing anesthetics Using any drug within last 24 hours which interfere with pain evaluation presence of any systemic diseases and mental disorders patients with hypermic primary second molars which require pulpectomy

Age
From **5 years** old to **8 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
We use block randomization with size of 10 to randomize treatment for the patients. According to the comparison of the two types of anesthetics, at first, the subjects were divided into two groups, A and B, based on which treatment they received in the first session.in each block of 10, 5 people randomly receive A treatment and 5 people receive B treatment. Randomization was performed using version 9 of SAS software.Based on this, considering that the sample size is 40, we had 4 blocks

of 10. In order to randomly assign the treatment to the patients right or left, a 10-shift permutation randomization was used again, considering that we indicated the right and left with letters C and D. in the previous randomization, we specified which anesthesia each person would receive. in this randomization, we specified which direction the anesthesia would be injected. based on this, we had random blocks of 10 that identified 5 on the right and 5 on the left.

Blinding (investigator's opinion)

Double blinded

Blinding description

All injections will be performed by a pediatric dentist who is not aware of anesthetic drug type and study method.Dentist will receive anesthetic drugs in the same boxes without name and will be marked as A and B. In this way, dentist and patient will not be aware of treatment type.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Guilan University of Medical Sciences

Street address

Deputy of Research and Technology, In front of 17 Sharivar Hospital, Shahid Siadati Ave., Namjo Ave.

City

Rasht

Province

Guilan

Postal code

41941-73774

Approval date

2020-07-29, 1399/05/08

Ethics committee reference number

IR.GUMS.REC.1399.225

Health conditions studied

1

Description of health condition studied

Anesthesia in pediatric pulpotomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Facial Image Scale(FIS)

Timepoint

Immediately after pulp exposure

Method of measurement

facial image scale graph

2

Description

Sound , Eye & Motor scale (SEM)

Timepoint

Immediately after pulp exposure

Method of measurement

patient behavior objective evaluation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group patients will receive 1.8 ml Articaine 4% infiltration injection in mandibular primary second molar and their tooth anesthesia during the pulp therapy will be evaluated. Tehran Daru Pakhsh will provide the drug.

Category

Treatment - Drugs

2

Description

Control group: In this group patients will receive 1.8 ml Lidocaine 2% Inferior alveolar nerve block injection and their anesthesia during the pulp therapy of mandibular primary second molar will be evaluated. Tehran Daru Pakhsh will provide the drug.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Special Dental Clinic Of Guilan University Of Medical Sciences

Full name of responsible person

Dariush Dorani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Naghipoor

Street address

6th floor, central building of the Gilan University of Medical Sciences, opposite Azodi stadium, Namjoo Street

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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

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Dr. Seyed Hedyeh Daneshvar

Position

Assistant professor of Pediatric Dentistry, Department of Pediatric

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data are shareable after making them unidentifiable

When the data will become available and for how long

accessibility starts from 6 month after being published

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers can use them by citing references.

From where data/document is obtainable

Dr. seyed hedyeh daneshvar dr.daneshvar@gums.ac.ir

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

There is no special process.

Comments