Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

Email address

dariushdorani92@gmail.com

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
Street address
Special Dental Clinic , Emam Khomeyni Blvd.
City
Rasht
Province
Guilan
Postal code
41941-73774
Phone
+98 13 3348 6406
Fax
+98 13 3348 6423
Email
dental@gums.ac.ir
Web page address
http://www.gums.ac.ir/dental

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
City
Rasht
Province
Guilan
Postal code
41446-56513
Phone
+98 13 3322 9599
Fax
+98 13 3332 2444
Email
research@gums.ac.ir
Web page address
http://www.gums.ac.ir/research
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
Street address
Dentistry faculty, Guilan medical sciences complex, Fuman_Saravan Highway
City
Rasht
Province
Guilan
Postal code
41941-73774
Phone
+98 13 3348 6406
Fax
+98 13 3348 6423
Email
dr.daneshvar@gums.ac.ir
Web page address
http://www.gums.ac.ir/dental

Person responsible for scientific 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
Street address
Dentistry faculty, guilan medical sciences complex, Fuman_Saravan Highway
City
Rasht
Province
Guilan
Postal code
41941-73774
Phone
+98 13 3348 6406
Fax
+98 13 3348 6423
Email
dr.daneshvar@gums.ac.ir
Web page address
http://www.gums.ac.ir/dental

Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dariush Dorani
Position
Dentistry Student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
No. 307 , Narges Ave. , Goldis Town , Ebnesina Street , Lakan Blvd. , Rasht
City
Rasht
Province
Guilan
Postal code
4147673866
Phone
+98 13 4469 1467
Fax
Email
Dariushdorani92@gmail.com

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