Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effect of 4% Articaine and 2% Lidocaine infiltration during maxillary primary molar teeth extraction for 6-12 year-old children

Protocol summary

Study aim

Comparison of the effect of 4% Articaine and 2% Lidocaine infiltration during maxillary primary molar teeth extraction for 6-12 year-old children

Design

In this randomized block clinical trial, 54 healthy children aged 6-12 years referred to the special clinic of Guilan Dental School who need to extract maxillary primary molars in both directions are selected. 2%lidocaine is used on one side and 4%articaine on the other side for local anesthesia of infiltration. Patients are randomly divided into two groups A and B.children select the appropriate face from Facial Image Scale after extraction. The pulse oximeter is used to record the baby's heartbeat while extracting teeth

Settings and conduct

Random block, 54 healthy children aged 6-12 years referred to the special clinic of Guilan Dental School who need to pull maxillary deciduous molars in both directions. 2% lidocaine is used on one side and 4% articaine on the other for local anesthesia of infiltration. Random sequences are placed in opaque sealed envelopes. Two blinds, an assistant evaluating the outcome, and the patient is unaware of the type of anesthetic.

Participants/Inclusion and exclusion criteria

Healthy cooperative children 6-12 years old who need to extract maxillary primary teeth - Parental consent - No allergic to anesthetic - No systemic problems - No drug that interferes with anesthesia

Intervention groups

Control group 1.8 ml 4% articaine with epinephrine 1: 1000000 . Control group 1.5 ml lidocaine 2% with epinephrine 1: 80000

Main outcome variables

Complete anesthesia of the palatal tissue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200725048194N1**
Registration date: **2022-04-09, 1401/01/20**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-09, 1401/01/20**
Update count: **0**

Registration date

2022-04-09, 1401/01/20

Registrant information

Name

Seyedeh Hediyeh Daneshvar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3332 8843

Email address

hedyehdaneshvar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-06, 1400/12/15

Expected recruitment end date

2022-06-05, 1401/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of 4% Articaine and 2% Lidocaine infiltration during maxillary primary molar teeth extraction for 6-12 year-old children

Public title
effect of 4% Articaine and 2% Lidocaine infiltration during maxillary primary molar teeth extraction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy children 6-12 years old who require primary maxillary molar extraction The child's cooperation is appropriate for dental treatment under local anesthesia (Class 3 or 4 Frankl scale) Consent of children's parents to participate in this study
Exclusion criteria:
Allergic reaction to anesthetic solutions Having a systemic problem that interferes with the use of epinephrine-containing anesthetics Receive any medication in the last 24 hours that interferes with the assessment of pain
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomize people into two groups A and B, based on the description of the work method, permutation block randomization with block size 6 is used. Based on the order in which people enter the study, part of the randomization process is given below. The complete file is available as an Excel file (SAS version 9 software was used for randomization): Seed: 21650415094698 Block sizes: 6 Actual list length: 54 block identifier, block size, sequence within block, treatment • 1, 6, 1, Group A • 1, 6, 2, Group B • 1, 6, 3, Group A • 1, 6, 4, Group B • 1, 6, 5, Group A • 1, 6, 6, Group B • 2, 6, 1, Group A To select the right and left based on the allocation specified in the previous section based on the order specified by considering the left with the letter L and the right with R, the order of selecting the direction will be as follows: Seed: 21650415094698 Block sizes: 6 Actual list length: 54 block identifier, block size, sequence within block, treatment • 1, 6, 1, Group R • 1, 6, 2, Group L • 1, 6, 3, Group R • 1, 6, 4, Group L • 1, 6, 5, Group R • 1, 6, 6, Group L • 2, 6, 1, Group R • 2, 6, 2, Group L • 2, 6, 3, Group L
Blinding (investigator's opinion)
Double blinded
Blinding description
Random sequences are placed in opaque sealed envelopes. Two blinds, an assistant evaluating the outcome, and the patient are unaware of the type of anesthetic. It is not possible for the dentist to blind the material because the injection method is different and the dentist subconsciously notices.
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
Namjoo St. - Shahid Siadati St. - Opposite to Shahrivar Hospital - Vice Chancellor for Research and Technology of Guilan University of Medical Sciences
City
Rasht
Province
Guilan
Postal code
4183815837
Approval date
2021-11-24, 1400/09/03
Ethics committee reference number
IR.GUMS.REC.1400.427

Health conditions studied

1

Description of health condition studied
Comparison of the effect of 4% Articaine and 2% Lidocaine infiltration during maxillary primary molar teeth extraction for 6-12 year-old children
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Palatal anesthesia by injecting articaine infiltration alone without injecting into the palatal area
Timepoint
after extraction
Method of measurement
Selecting a higher number (1 to 5) of the Smiley Image Scale (FIS) indicates that the child is more dissatisfied.

2

Description
heart beat
Timepoint
during tooth extraction
Method of measurement
pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Control group: In the first session for group A patients, injection of 1.8 ml of 4% articaine with epinephrine 1: 1000000 (Daru Pakhsh Company, Tehran, Iran) as buccal infiltration is used and and in the second session, which is at least one week away from the first session, 1.8 ml of 2% lidocaine 2% with epinephrine 1: 80,000 as buccal infiltration is used.
Category
Treatment - Drugs

2

Description
Control group: In the first session for group B patients, injection of 1.8 ml of 2% lidocaine 2% with epinephrine 1: 80,000 (Daru Pakhsh Company, Tehran, Iran) as buccal infiltration is used and and in the second session, which is at least one week away from the first session, 1.8 ml of 4% articaine with epinephrine 1: 1000000 as buccal infiltration is used.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Specialized Dental Clinic, Rasht
Full name of responsible person
Seyedeh Hedyeh Daneshvar
Street address
Specialized Dental Clinic, after Farhang Square,Imam Street, Rasht
City
Rasht
Province
Guilan
Postal code
1245632145
Phone
+98 13 3332 0060
Email
ib@gums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Seyedeh Hedyeh Daneshvar
Street address
Specialized Dental Clinic, after Farhang Square,Imam Street, Rasht
City
Rasht
Province
Guilan
Postal code
1245632145
Phone
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Email
ib@gums.ac.ir
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
Seyedeh Hedyeh Daneshvar
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Specialized Dental Clinic, after Farhang Square,Imam Street, Rasht
City
Rasht
Province
Guilan
Postal code

1245632145

Phone

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Email

dr.daneshvar@gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Seyedeh Hedyeh Daneshvar

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Maryam Adham Haghighi Pour

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Darvish Sohrab Alley۹Motahhari St. Rasht

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Province

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Email

maryamad74@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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Consents and work results for each person

When the data will become available and for how long

Start access 1 month after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Frequency and percentage are used to describe qualitative data And for quantitative data, mean and standard deviation will be used In addition, suitable descriptive tables and graphs will be used for both measurement scales. Shapiro-Wilk test is used to check the normality of the distribution of the groups and Levene test is used to homogenize the variances. To investigate the relationship and compare groups if the relevant assumptions are made from paired t-test and paired t-test and Generalized estimating equations (GEE) and if the assumptions are not made from Wilcoxon test and in case of no hypotheses for the GEE test, the appropriate conversions proposed by SPSS software (such as square root and logarithm) will be used to establish the hypotheses. . The software used will be spss version 26. Significance level in all tests will be considered 0.05.

From where data/document is obtainable

Maryam Adham Haghighi Pour: maryamad74@gmail.com
Dr. Seyedeh Hedye Daneshvar: dr.daneshvar@gums.ac.ir

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

Send text to the email mentioned in the previous section using the data.

Comments