

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 blinks, 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 Hedyeh 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 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 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

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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

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

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##### Postal code

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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**

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**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Specialized Dental Clinic, after Farhang Square, Imam Street, Rasht

**City**

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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 Alley, Motahhari St. Rasht

**City**

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**Province**

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**Postal code**

4183815836

**Phone**

+98 13 3333 1866

**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 Hedyeh 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**