

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of palatal anesthetic efficacy of 4% articaine versus 2% lidocaine in buccal infiltration of maxillary first primary molar.

Protocol summary

Study aim

Determination of the Effect of Injection of Bacterial Infiltration of 4% Articaine and 2% lidocaine Solutions on Palatal tissue Anesthesia in maxillary primery molars extraction

Design

Clinical trial with control group, parallel, randomized, with blinded postoperative care and outcome assessment

Settings and conduct

A total of 44 healthy children were selected from patients that admitted to pediatric dentistry department of Zahedan college of dentistry who needed bilateral extraction of primery maxillary molars. In half of the children, randomly in the first session, lidocaine and in the second session, articaine and in the other half vice versa were used. The objective pain response of the child was recorded by the trained person who was blind to the medicine that used and the subjective response of the pain was recorded by the child himself and after the explanation given by the assistant.

Participants/Inclusion and exclusion criteria

Age between 6 to 8 years No systemic disease and mental retardation No allergy No history of dentistry treatment

Intervention groups

Use of each studied anesthetics for one side of the patient In this study, each child is compared with her/his self.

Main outcome variables

Score of objective pain index; Score of subjective pain index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180220038801N1**

Registration date: **2018-03-10, 1396/12/19**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-10, 1396/12/19**

Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

Forough Akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 1814

Email address

akbariforooghdds@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of palatal anesthetic efficacy of 4% articaine versus 2% lidocaine in buccal infiltration of maxillary first primary molar.

Public title

Comparison of the effect of two different anesthetics on

palatal tissue numbness in children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Need of bilateral maxillary molars extraction Patient cooperation
Exclusion criteria:
 Systemic disease Mental retardation History of previous dentistry treatment Allergy to Anesthetic medicine Abcess in location

Age
From **6 years** old to **8 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
 Target sample size: **44**
 More than 1 sample in each individual
 Number of samples in each individual: **2**
 The primary molar on one side of the patient is randomly selected as the case group and the other side as the control group.
 Actual sample size reached: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
In each patient, the tooth of the case and control group is selected randomly using the coin.

Blinding (investigator's opinion)
Double blinded

Blinding description
The investigator and his assistant are unaware of the type of anesthesia and the third person will prepare anesthetic Cartridges for injections. The patient and his parents did not know the type of medicine used to numb any quadrant.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical

Sciences
Street address
 ZaUMS Main campus, Jenat Blvd., Zahedan, Sistan and Baluchestan, Iran
City
 Zahedan
Province
 Sistan-va-Balouchestan
Postal code
 9816743463
Approval date
 2018-01-14, 1396/10/24
Ethics committee reference number
 IR.ZAUMS.REC.1396.339

Health conditions studied

1

Description of health condition studied

The amount of pain during tooth extraction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Objective pain index

Timepoint

5 minutes after injection, while palatal gingiva decollation

Method of measurement

SEM scale

2

Description

Subjective pain index

Timepoint

Immediately after treatment

Method of measurement

FPS scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Infiltration injection of 2% articaine

Category

Treatment - Drugs

2

Description

Control group: Infiltration injection of 4% lidocaine

Category

Treatment - Drugs

Country of origin**Type of organization providing the funding**

Academic

Recruitment centers**1****Recruitment center****Name of recruitment center**

Zahedan university of medical sciences

Full name of responsible person

Forough Akbari

Street address

College of dentistry , Eastern Azadegan St. , Zahedan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Zahedan 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

Person responsible for general inquiries**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Nastaran Seyed Samak

Position

Dentistry student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Assistant professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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