Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 netween 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: Infilltration injection of 2% articaine

Category

Treatment - Drugs

2

Description

Control group: Infilltration injection of 4% lidocaine

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Zahedan university of medical sciences
Full name of responsible person
Forough Akbari
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College of dentistry , Eastern Azadegan St. , Zahedan
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Sponsors / Funding sources

1

Sponsor
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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
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
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Position
Dentistry student
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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