

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The anesthetic effectiveness of mandibular buccal infiltration with articaine compared to mandibular block anesthesia with lidocaine in pulpotomy of second primary molars.

Protocol summary

Summary

Articaine efficacy in primary second molar anesthesia
Objectives: Comparison of articaine buccal infiltration and lidocaine inferior alveolar nerve block for pulpotomy of second primary mandibular molars. Design: Controlled clinical trial Setting and conduct: after achieving informed consent from patient's parents, in each treatment session, one method will be used in one side of the mouth. For evaluation of child's pain and behavior during injection and treatment, Faces Pain Scale and Modified Behavioral Pain Scale will be used respectively. Major Inclusion and Exclusion criteria: Intervention: Infiltration method will be used with 1.8 ml 4% articaine solution with epinephrine 1: 100000 in intervention group; Inferior alveolar nerve block method will be used with 2% lidocaine solution with 1: 80000 epinephrine in control group. Major Inclusion and Exclusion criteria: 5-8 years old subject; Children that in pre-study visit according to frankle scale for behaviors classified as Class 3 or 4 and consider as cooperative; Two mandibular primary second molars that needs pulpotomy treatment; subjects did not satisfy the inclusion criteria; History of spontaneous or nocturnal pain; gingival abscess or sinus tract will be excluded from study. Intervention: intervention group infiltration injection, with one 1.8 ml cartridge of 4% articaine with 1: 100000 epinephrine; Control group inferior alveolar nerve block, with one 1.8 ml of 2% lidocaine with 1: 80000 epinephrine Main outcome measures: Pain during pulpotomy treatment; child sensation during injection

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042321484N2**
Registration date: **2015-10-06, 1394/07/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-10-06, 1394/07/14

Registrant information

Name

Zahra Khosravi

Name of organization / entity

Tehran University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-07-06, 1394/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The anesthetic effectiveness of mandibular buccal infiltration with articaine compared to mandibular block anesthesia with lidocaine in pulpotomy of second

primary molars.

Public title
Articaine efficacy in primary second molar anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 5-8 years old subject (Children under 5 years will be excluded from trial because of problem in communication and differentiation between pain and other negative reaction. children older than 8 years will be excluded because of possible physiologic root resorption); Children that consider as cooperative in pre-study visit (According to frankle scale for behaviors classified as Class 3: child is cooperative, but somewhat reluctant/ shy; Class 4: child is completely cooperative and even enjoys the experience); Two mandibular primary second molars that needs pulpotomy treatment; No history of allergic reaction to local anesthetics and sulfites; No systemic disease that don not let the dentist treat under local anesthesia; No pain killer taken for at least 24 hour before treatment. Exclusion criteria: subjects did not satisfy the inclusion criteria; History of spontaneous or nocturnal pain; gingival abscess or sinus tract; Radiographic sign of PDL widening, reduction in supporting bone density, furcation radiolucency or pathologic root resorption.

Age
From **5 days** old to **8 days** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of Tehran University of Medical Sciences

Street address

Keshavarz street.Qods street,The central building of Tehran University of Medical Sciences,6th floor,The ethics committee in research

City

tehran

Postal code

Approval date

2015-08-18, 1394/05/27

Ethics committee reference number

IR.TUMS.REC.1394.610

Health conditions studied

1

Description of health condition studied

Local anaesthesia

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes

1

Description

Pain during pulpotomy treatment

Timepoint

During intervention

Method of measurement

Modified Taddio's behavioural pain scale

2

Description

Child sensation during injection

Timepoint

During intervention

Method of measurement

Wong-Baker FACES pain rating scale

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention Group: Before treatment, benzocaine 20% topical anesthetic gel (Benzotop-DFL.Industria e Comercio) will be applied on dried oral mucosa in

injection site area with cotton roll for 1 minute. in test group, infiltration method will be used with 1.8 ml 4% articaine solution with epinephrine 1: 100000 (Septocaine® Septodont Co- France). Injection will be done with a standard aspirating dental syringe and 20 mm, 30 gauge injection needle with injection rate of 1 ml/min. maximum application dose for Articaine is 7 mg/kg.

Category

Treatment - Other

2

Description

Control group: Before treatment, benzocaine 20% topical anesthetic gel (Benzotop-DFL. Industria e Comercio) will be applied on dried oral mucosa in injection site area with cotton roll for 1 minute. Inferior alveolar nerve block method will be applied with 2% lidocaine solution with 1:80000 epinephrine (Persocaine® Darou Pakhsh Co-tehran, Iran). Injection will be done with a standard aspirating dental syringe and 20 mm, 30 gauge injection needle with injection rate of 1 ml/min. maximum application dose for lidocaine is 4 mg/kg.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Department of Dentistry Faculty-Tehran
University of Medical Sciences

Full name of responsible person

Dr.zahra khosravi

Street address

School Of Dentistry Of Tehran University Of Medical
Sciences, North Kargar Street, Enghelab Square,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Dr. Zahra Khosravi

Street address

Number 218, Fatemi street, North Kargar Street,
Enghelab Square

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Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Investigator

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Pediatric department of dentistry faculty-tehran
university of medical sciences

Full name of responsible person

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Position

Postgraduate student of pediatric dentistry

Other areas of specialty/work

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Full name of responsible person

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty