

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the effect of 4% Articaine Buccal Infiltration and 2% Lidocaine Inferior Alveolar Nerve Block on Pain Perception and Behavioral Feedback of Children during Pulp Treatment of mandibular second primary molars

Protocol summary

Study aim

Comparison of articaine buccal infiltration and lidocaine inferior alveolar nerve block for pulpotomy of second primary mandibular molars

Design

4-6 years old children who are healthy and have good cooperation and need bilateral mandibular second primary molar pulp therapy

Settings and conduct

This clinical trial study on prevention of decay progress, will be done in Tabriz Dentistry Faculty. The samples will be 38 individuals in the age group of 4-6 years. After obtaining 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, Face Scale and Visual Analogue Scale will be used respectively.

Participants/Inclusion and exclusion criteria

Major Inclusion and Exclusion criteria: 4-6 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 groups

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

Main outcome variables

Pain during pulpotomy treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100125003168N5**

Registration date: **2018-02-07, 1396/11/18**

Registration timing: **retrospective**

Last update: **2018-02-07, 1396/11/18**

Update count: **0**

Registration date

2018-02-07, 1396/11/18

Registrant information

Name

Leila Erfanparast

Name of organization / entity

Tabriz University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 5965

Email address

erfanparastl@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-01-24, 1396/11/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of 4% Articaine Buccal Infiltration and 2% Lidocaine Inferior Alveolar Nerve Block on Pain Perception and Behavioral Feedback of Children during Pulp Treatment of mandibular second primary molars

Public title

Articaine efficacy in primary second molar anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

4-6 year old children, attending to Department of Pediatric Dentistry of Tabriz University of Medical Sciences Children who are 3 or 4 frankle in terms of cooperation No history of allergic reaction to local anesthesia No systemic disease that don not let the dentist treat under local anesthesia No pain killer taken for at least 24 hour before treatment Two mandibular primary second molars that needs pulpotomy treatment patient collaboration and acceptance of treatment

Exclusion criteria:

History of spontaneous or nocturnal pain Gingival abscess or sinus tract Furcation radiolucency

Age

From **4 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **38**

More than 1 sample in each individual

Number of samples in each individual: **2**

Two mandibular second primary molars are one on one side and the other on the other side that need pulp therapy.

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups of 2 and 1. At the first meeting, for all patients in group 1, infiltration is performed on the second right molar, and in the next session of the treatment, the block method will be performed on the opposite side.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research vice-chancellor, Tabriz University of Medical Sciences

Street address

Daneshgah Ave. - Golgasht St.-Tabriz University of Medical Scienc

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2018-01-22, 1396/11/02

Ethics committee reference number

IR.TBZMED.REC.1396.967

Health conditions studied**1****Description of health condition studied**

pulpits

ICD-10 code

K04.0

ICD-10 code description

NOS-acute-chronic (hyperplastic)(ulcerative)-irreversible-reversible

Primary outcomes**1****Description**

Pain

Timepoint

During intervention

Method of measurement

(Sound, Eye, Motor)

2**Description**

Child sensation during injection

Timepoint

During intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 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 - Drugs

2

Description

Control group: 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

Tabriz Faculty of Dentistry-Department of Pediatric Dentistry

Full name of responsible person

Leila Erfanparast

Street address

Daneshgah Ave- Golgasht St.-Tabriz Univdrstity of Medical Sciences-Faculty of Dentistry-Department of Pediatric Dentistry

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 5965

Fax

+98 41 3334 6977

Email

Erfanparastl@tbzmed.ac.ir

Web page address

<http://dentistryfac.tbzmed.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Reasearch Vice-Chancellor- Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

Street address

Daneshgah Ave- Golgasht St.- Main Buliding-3rd floor

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 4333 0310

Fax

+98 41 3334 6977

Email

Erfanparastl@tbzmed.ac.ir

Web page address

<http://dentistryfac.tbzmed.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Reasearch Vice-Chancellor- Tabriz 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

Faculty of Dentistry

Full name of responsible person

Leila Erfanparast

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Daneshgah Ave-Golgasht St.- Faculty of Dentistry- Department of Pediatric Dentistry

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 1335 5965

Fax

+98 41 1334 6977

Email

Erfanparastl@tbzmed.ac.ir

Web page address

<http://dentistryfac.tbzmed.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Dentistry

Full name of responsible person

Leila Erfanparast

Position

Associate Professore

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Daneshgah Ave-Golgasht St-Tabriz University of
Medical Sciences-Faculty of Dentistry

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 1335 5965

Fax

+98 41 1334 6977

Email

Eranparastl@tbzmed.ac.ir

Web page address

<http://dentistryfac.tbzmed.ac.ir>

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Dentistry

Full name of responsible person

Leila Erfanparast

Position

Associated Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Daneshgah Ave-Golgasht St-Tabriz University of
Medical Sciences-Faculty of Dentistry

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

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Fax

+98 41 1334 6977

Email

Erfanparastl@tbzmed.ac.ir

Web page address

<http://dentistryfac.tbzmed.ac.ir>

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