

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comprison of anesthetic efficacy of Buccal Infiltration versus Inferior Alveolar Nerve block for Pulpotomy in Mandibular Second Primary Molars in sedated patients

Protocol summary

Study aim

Comprison of anesthetic efficacy of Buccal Infiltration versus Inferior Alveolar Nerve block for Pulpotomy in Mandibular Second Primary Molars in sedated patients

Design

All treatment steps were performed by a pediatric dentist .Type of injection was performed randomly with a coin on each side of the jaw.

Settings and conduct

Shahid Beheshti Faculty of Dentistry Fellowship
Department

Participants/Inclusion and exclusion criteria

inclusion criteria :3-6 year-old non-cooperative children (negative or completely negative based on Frankel scale)
A child with ASA Class I systemic status with 2 mandibular decayed second molar teeth. The patient needs to undergo at least 2 similar dental treatment sessions
Exclusion criteria: Radiographic signs such as internal and external pathological resorption, radiolucency of the periapical area or physiological resorption of more than 1/3 of the root length.

Intervention groups

First, oral midazolam is administered . After 30 minutes, sedation with ketamine and propofol drugs will be started in a titrated manner. In each treatment session, one side of the jaw will be anesthetized randomly with one of the anesthetic techniques with 1/2 carpool of 2% lidocaine or buccal infiltration with 1/3 carpool of articaine 4%. The dental treatment performed will be the pulpotomy of the second molar tooth.After removing the caries and inflamed pulp of the coronal area, formocresol will be used to fix the pulp of the orifice area. After placing Zonalin in the pulp chamber, the tooth will be restored with a stainless steel veneer and glass ionomer cement. The time to evaluate the behavioral and physiological parameters will be immediately after receiving the sedative (T0), during anesthesia injection

(T1), during pulp exposure (T2) and after transferring the child to the recovery room (T3).

Main outcome variables

The effectiveness of both techniques is similar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190313043046N2**

Registration date: **2023-06-13, 1402/03/23**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-13, 1402/03/23**

Update count: **0**

Registration date

2023-06-13, 1402/03/23

Registrant information

Name

Taraneh Faghihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 7571

Email address

trnfaghihi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-11, 1402/03/21

Expected recruitment end date

2023-07-12, 1402/04/21

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comprison of anesthetic efficacy of Buccal Infiltration versus Inferior Alveolar Nerve block for Pulpotomy in Mandibular Second Primary Molars in sedated patients

Public title
Comprison of anesthetic efficacy of Buccal Infiltration versus Inferior Alveolar Nerve block for Pulpotomy in Mandibular Second Primary Molars in sedated patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
3-6 year-old non-cooperative children (negative or completely negative based on Frankel scale) A child with ASA Class I systemic status has 2 mandibular decayed second molar teeth on the right and left sides, without clinical or radiographic symptoms, with the possibility of pulpotomy after caries removal. The patient needs to undergo at least 2 similar dental treatment sessions with local anesthesia
Exclusion criteria:
History of any clinical symptoms such as spontaneous pain, soft tissue swelling, fistula, mobility of primary second molar teeth or abnormal bleeding during access cavity preparation. Radiographic symptoms such as internal and external pathological resorption, radiolucency of the periapical area or furcation or physiological resorption of more than 1/3 of the root length. History of cold in the last 14 days Any adverse drug reaction to local anesthetics or sedatives

Age
From **3 years** old to **6 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Sequentially numbered, opaque, sealed envelopes were used in this study for random allocation which were kept by the Nurse of fellowship department

Blinding (investigator's opinion)
Double blinded

Blinding description
patient and analyzer are blind

Placebo
Not used

Assignment

Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti Dental School, Daneshjoo Blvd, Shahriyari sq, Evin, Chamran Highway, Tehran-Iran
City
Tehran
Province
Tehran
Postal code
1983969411
Approval date
2023-06-10, 1402/03/20
Ethics committee reference number
IR.SBMU.DRC.REC.1402.006

Health conditions studied

1

Description of health condition studied
anesthetic efficacy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Comprison of anesthetic efficacy of Buccal Infiltration versus Inferior Alveolar Nerve block
Timepoint
Comparison of the effectiveness of infiltration and block anesthesia technique in two treatment sessions
Method of measurement
according to Nonverbal pain scale revised

Secondary outcomes
empty

Intervention groups

1

Description
Intervention group: Randomly a second primary molar on one side of the jaw is anesthetized by buccal infiltration

technique with Articaine.

Category

Treatment - Other

2

Description

Intervention group: Randomly, the second molar tooth on the opposite side of the jaw is anesthetized using the lower alveolar nerve block method with Lidocaine.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric dentistry fellowship clinic of Shahid Beheshti Dental School

Full name of responsible person

Taraneh Faghihi

Street address

Shahid Beheshti Dental School, Daneshjoo Blvd, Shahriyari sq, Evin, Chamran Highway, Tehran-Iran

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2217 5350

Email

dentit@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Masoud Fallahinejad

Street address

Shahid Beheshti Dental School, Daneshjoo Blvd, Shahriyari sq, Evin, Chamran Highway, Tehran-Iran

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2217 5350

Email

dentit@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

1

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Taraneh Faghihi

Position

Pediatric Dentist

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Province

Tehran

Postal code

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Phone

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Email

trnfaghihi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

taraneh faghihi

Position

pediatric dentist

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Shahid Beheshti Dental School, Daneshjoo Blvd, Shahriyari sq, Evin, Chamran Highway, Tehran-Iran

City

tehran

Province
Tehran
Postal code
198396941
Phone
+98 21 2217 5350
Email
trnfaghihi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
taraneh faghihi
Position
pediatric dentist
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Shahid Beheshti Dental School, Daneshjoo Blvd,
Shahriyari sq, Evin, Chamran Highway, Tehran-Iran
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tehran
Province
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Postal code
1983969411
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+98 21 2217 5350

Email
trnfaghihi@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

only results of the study would be identified

When the data will become available and for how long

from summer 2023 they would be accessible

To whom data/document is available

everyone

Under which criteria data/document could be used

no specific limitations

From where data/document is obtainable

trnfaghihi@gmail.com

What processes are involved for a request to access data/document

maximum 2 weeks after sending request to the email

Comments