

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Anesthetic Efficacy of Buccal Infiltration of 4% Articaine compared to Block Injection with 2% Lidocaine for Extraction of Mandibular Primary Molars

Protocol summary

Study aim

the aim of this study is to evaluate and compare the anesthetic efficacy of a single buccal infiltration of 4% articaine with routine infra dental block using 2% lidocaine during the injection and extraction of primary mandibular molars

Design

A prospective, randomized, blinded, controlled clinical trial with a parallel group design of 100 patients was conducted.

Settings and conduct

one group(treatment group)receive mandibular infiltration with articaine 4% with intrapapillary infiltration for lingual analgesia; the other group(control group) receive an inferior dental block with 2% lidocaine supplemented with long buccal infiltration.The anesthetic solution in both groups is delivered using a dental syringe and a 15 mm long 27-gauge needle and with standardized rate of injection (to ~1 ml/min) in Shahid Beheshti dental school and pediatric dentists office in Tehran.The pain assessment is carried out using Wong-Baker Faces Pain Rating Scale (W-BFSR) and Frankl Behaviour Rating Scale (FBRs).

Participants/Inclusion and exclusion criteria

Inclusion Criteria:1) Having a mandibular primary molar tooth that required extraction 2)Medically fit (ASA I, II) 3) Mentally capable of communication 4)A good understanding of persian 5)The tooth should have had no history of infection (abscess) or swelling or pain
Exclusion Criteria:1)Medical)History of significant behaviour management problems3)Evidence of infection or abscess near the proposed injection site

Intervention groups

the pain during of injection and treatment is being assessed in case group which received mandibular infiltration with 4% articaine, with intrapapillary infiltration and control group which received an infra

dental block with 2% lidocaine supplemented by long buccal infiltration.

Main outcome variables

The pain during treatment/The pain during injection/ Method of injection/Gender/ Age

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220129053868N1**

Registration date: **2023-03-01, 1401/12/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-01, 1401/12/10**

Update count: **0**

Registration date

2023-03-01, 1401/12/10

Registrant information

Name

Bornadokht Bazghandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8860 0098

Email address

b.bornadokht@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-27, 1401/12/08

Expected recruitment end date

2023-06-21, 1402/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Anesthetic Efficacy of Buccal Infiltration of 4% Articaine compared to Block Injection with 2% Lidocaine for Extraction of Mandibular Primary Molars

Public title

Anesthetic Efficacy of Infiltration of Articaine

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having Mandibular Primary Molars that required extraction medically fit(ASA I,II) Mentally capable of communication A good understanding of Persian Having no history of pain or infection (abscess) or swelling

Exclusion criteria:

Medically and mentally compromised children History of significant behaviour management problems Evidence of infection or abscess near the proposed injection site

Age

From **4 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Permutation

Blinding (investigator's opinion)

Double blinded

Blinding description

informing parents not children

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

No. 34, South Shiraz Ave., Alikhani Blvd.

City

Tehran

Province

Tehran

Postal code

1436937554

Approval date

2021-12-27, 1400/10/06

Ethics committee reference number

IR.SBMU.DRC.REC.1400.107

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

Anesthetic efficacy for extraction of mandibular primary molars

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The pain during treatment

Timepoint

After injection

Method of measurement

Frankl Behaviour Rating Scale(FBRS), Wong- Baker Faces Pain Rating Scale (W-BFSR)

Secondary outcomes**1****Description**

The Pain during the treatment

Timepoint

After tooth extraction

Method of measurement

Visual Analogue Scale

Intervention groups**1****Description**

Intervention group: buccal infiltration of 4% articaine epinephrine 1/200000(Dentacain 200, Exir Pharmaceutical Co.)

Category

Treatment - Surgery

2

Description

Control group: Block Injection with 2% Lidocaine
epinephrine 1/100000(Persocaine-E, Darou Pakhsh)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentistry Faculty of Shahid Beheshti

Full name of responsible person

Sanaz Kamareh

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Daneshjou Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

School of Dentistry, Shahid Beheshti University of
Medical science, Daneshjou Blvd, Daneshgah (Shahriari)
Square, Evin, Shahid Chamran Highway

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1983963113

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Email

Zarghi@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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Bornadokht Bazghandi

Position

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sanaz Kamareh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Pediatric Dentist

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Bornadokht Bazghandi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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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

The recorded data can be shared based on the studied indicators after identifying the sample individuals, these data include the numbers and scores from the Wong-Baker Faces Pain Rating Scale, Frankl Behaviour Rating Scale, Visual Analogue Scale, as well as the results of statistical analysis of these data.

When the data will become available and for how long

e.g. strating 6 months after publication

To whom data/document is available

researchers working in academic and scientific institutes can apply for access to the data

Under which criteria data/document could be used

performing statistical analyzes to compare data with other studies in this field is one of the conditions for access to data. so the analysis must be appropriate to the type of data recieved from the applicant.

From where data/document is obtainable

applications can obtain access to the data by submitting a request to the following emails in due time. moderator: bornadokht bazghandi

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

After submitting the request by email and also sending the request to whatsapp of the specified person, the applicant will be able to access the information within one week after submitting he request, if she has the requisite conditions.

Comments