Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
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School of Dentistry,Shahid Beheshti University of Medical science,Daneshjoo Blvd,Daneshgah(Shahriari) Square,Evin,Shahid Chamran Highway
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1983963113
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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 updating data

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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