

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the Effectiveness of Benzocaine gel and Lidocaine-Prilocaine cream on Pain and Anxiety Reduction due to Dental Infiltration Anesthesia in Primary Upper Teeth

Protocol summary

Study aim

Comparison of the effectiveness of Benzocaine gel and Lidocaine- Prilocaine cream on pain and anxiety reduction due to dental infiltration injection in upper primary posterior teeth

Design

A double- blinded third phase clinical trial with 2 experimental groups and cross over group design of 21 patients

Settings and conduct

After specimens selection, children are randomly divided into two groups A (n = 11) and B (n = 10). In group A, in the first session of treatment after drying the mucosa, 0.5 g of lidocaine-5% surface anesthetic will be applied for 3 minutes and in the second session 0.5 g of benzocaine surface anesthesia gel will be applied for 30 seconds. While the group B, will go to a vise versa process. The child is not aware of the type of topical anesthesia agents. After application of topical anesthesia, infiltration injection is performed. In both sessions, before using topical anesthesia, during the injection, and finally after the injection, the child's heart rate is measured by the pulse oximeter and the reactions during the injection is recorded by the CPS Scale. Wong Baker Facial Pain Scale(wbfps) is used for recording the pain due to injection. The outcome adjudicator is not aware of the type of experimental agent .

Participants/Inclusion and exclusion criteria

4 to 9 years old children Children without systemic problems Children without history of previous dental treatment Children requiring two symmetric posterior upper primary molars infiltration injection

Intervention groups

In group A, in the first session of treatment, Lidocaine-Prilocaine 5% (EMLA) will be used for 3 minutes and in the second session, Benzocaine will be used for 30 seconds, while for the group B, Benzocaine gel will be

used on oral mucosa in the first visit and in the second one we will use lidocaine-prilocaine cream.

Main outcome variables

Type of topical anesthesia; Heart rate; CPS scale; WBFPS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210908052409N1**

Registration date: **2022-01-24, 1400/11/04**

Registration timing: **retrospective**

Last update: **2022-01-24, 1400/11/04**

Update count: **0**

Registration date

2022-01-24, 1400/11/04

Registrant information

Name

Bardia Hasani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2269 3417

Email address

bardia.hasani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-25, 1399/07/04

Expected recruitment end date

2021-02-22, 1399/12/04

Actual recruitment start date

2020-09-25, 1399/07/04
Actual recruitment end date
2021-02-23, 1399/12/05
Trial completion date
2021-02-23, 1399/12/05

Scientific title

Comparison of the Effectiveness of Benzocaine gel and Lidocaine- Prilocaine cream on Pain and Anxiety Reduction due to Dental Infiltration Anesthesia in Primary Upper Teeth

Public title

Comparison of the Effectiveness of Benzocaine gel and Lidocaine- Prilocaine cream on Pain and Anxiety Reduction due to Dental Injection in Primary Teeth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

4-9 years old children
Children without systemic diseases
Children without history of previous dental treatment
Requiring two symmetric posterior primary upper teeth infiltration injection

Exclusion criteria:

Age

From **4 years** old to **9 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **21**
More than 1 sample in each individual
Number of samples in each individual: **2**
Upper buccal gingiva in both side of each patient
Actual sample size reached: **21**
More than 1 sample in each individual
Actual sample size in each individual: **2**
Upper buccal gingiva in both side of each patient

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant is not aware of the type of topical anesthesia before dental injection. Also , a dental assistant as an outcome adjudicator doesn't know about the type of experimental agent .

Placebo

Not used

Assignment

Crossover

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

School of Dentistry, Shahid Beheshti University of Medical Sciences, Daneshjoo Blvd., Daneshgah (Shahriari) Square, Evin, Shahid Chamran Highway

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Province

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Postal code

1983969411

Approval date

2020-08-25, 1399/06/04

Ethics committee reference number

IR.SBMU.DRC.REC.1399.043

Health conditions studied

1

Description of health condition studied

Pain and anxiety due to anesthesia infiltration injection in pediatric dentistry

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The perceived pain degree using Wong Baker Faces Pain scale(wbfps), the assessed pain and anxiety using children's Hospital of Eastern Ontario Pain Scale (CPS), heart rate ratio using pulse oximeter

Timepoint

Recording the degree of perceived pain after injection using Wong Baker Facial Pain Scale(wbfps) . Pain and anxiety assessment using CPS Scale during injection. Assessment of heart rate before, during and after injection using pulse oximeter device .

Method of measurement

Recording the degree of perceived pain after injection using Wong Baker Facial Pain Scale . Pain and anxiety assessment using CPS Scale during injection. Assessment of heart rate before, during and after injection using pulse oximeter device .

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: In this group , in the first session of treatment after drying the mucosa, 0.5 g of lidocaine-5% surface anesthetic will be applied for 3 minutes and in the second session 0.5 g of benzocaine surface anesthesia gel will be applied for 30 seconds. The child has upright position with headsupport and he/she is not aware of the type of topical anesthesia agents. After application of topical anesthesia, infiltration injection is performed. In both sessions, before using topical anesthesia, during the injection, and finally after the injection, the child's heart rate is measured by the pulse oximeter and the reactions during the injection is recorded by the CPS Scale. Wong Baker Facial Pain Scale is used for recording the pain due to injection. The outcome adjudicator is not aware of the type of experimental agent .

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group: In this group , in the first session of treatment after drying the mucosa, 0.5 g of benzocaine surface anesthesia gel will be applied for 30 seconds and in the second session 0.5 g of lidocaine-5% surface anesthetic will be applied for 3 minutes. The child has upright position with headsupport and he/she is not aware of the type of topical anesthesia agents. After application of topical anesthesia, infiltration injection is performed. Same as the previos group, in both sessions, before using topical anesthesia, during the injection, and finally after the injection, the child's heart rate is measured by the pulse oximeter and the reactions during the injection is recorded by the CPS Scale. Wong Baker Facial Pain Scale is used for recording the pain due to injection. The outcome adjudicator is not aware of the type of experimental agent .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric ward of school of dentistry, Shahid Beheshti University of Medical Science

Full name of responsible person

Kiana Poorzandpoush

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School of Dentistry, Shahid Beheshti University of Medical Sciences, Daneshjoo Blvd., Daneshgah (Shahriari) Square, Evin, Shahid Chamran Highway

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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 Sciences, Daneshjoo Blvd., Daneshgah (Shahriari) Square, Evin, Shahid Chamran Highway

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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

70

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

Kiana Poorzandpoush

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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

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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 reported from the Wong Baker FACES Pain Rating Scale, Houpt Scale, and numbers recorded from the finger pulse oximeter at specified times, as well as the results of statistical analysis of these data.

When the data will become available and for how long

e.g., starting 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 received from the applicant.

From where data/document is obtainable

Applicants can obtain access to the data by submitting a request to the following emails in due time. Moderator: Bardia Hasani Email address: bardia.hasani@gmail.com WhatsApp number: +989012879632

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 the request, if she has the requisite conditions.

Comments