Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of efficacy of Pre-Cooling and Topical Anesthetic Gel on the pain perception of pediatric patients during palatal injection

Protocol summary

Study aim

Comparison of efficacy of Pre-Cooling and Topical Anesthetic Gel on the pain perception of Children during palatal injection

Design

This study is based on community-based and pragmatic, split-based, double-blind clinical trials. The number of samples in each group is 14 and in total 28 samples. Each half-jaw is randomly assigned to the case group (cold) and control (gel). The pain intensity of the injections is evaluated by Mann-U-Whitney test in two methods.

Settings and conduct

Injection and dental work of both sides are done at a meeting in Pediatric department of dental school, Islamic Azad University of Tehran. After drying the tissue with cotton on one side, 20% benzocaine gel and the other side of the ice were used for 1 minute each. Anesthesia is performed by the first practitioner (pediatric dentist) using 2% Lidocaine anesthetic and Epinephrine 1/100,000 manufactured by Iran Daroopakhsh with a 30 gauge needle and 16 mm of length. The second operator, which is blind to the group of the study, will examine the child's behavior during an injection with SEM scale (sound, eye and motor). At the end of each of the injections, the child is asked to rate the amount of pain felt on the Wange-Baker scale.

Participants/Inclusion and exclusion criteria

No history of systemic diseases, phobias from injections, allergies to anesthetic substance, abscess and child be cooperative (Frankel's grade 1 or 2) and the need for bilateral palatal injection for routine dentistry such as extraction, dental preparation for SSC and wearing rubberdam for pulpotomy and pulpectomy.

Intervention groups

Intervention group: Use of ice that will be prepared by emptying the lidocaine cartridge and filling it with water and placing it in freezer. Control group: use of prime gel (20% benzoycane gel) manufactured by the prime dental company of America.

Main outcome variables

The rate of pain caused by injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180519039722N1**
Registration date: **2018-07-08, 1397/04/17**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-08, 1397/04/17**
Update count: **0**

Registration date

2018-07-08, 1397/04/17

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-13, 1397/03/23

Expected recruitment end date

2018-07-14, 1397/04/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of Pre-Cooling and Topical Anesthetic Gel on the pain perception of pediatric patients during palatal injection

Public title

Effect of pre-cooling injection site on pain perception

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Co-operative children (Frankl's rating scales III and IV) Requiring bilateral palatal injection for routine dental work such as extraction, dental preparation for SSC, pulpotomy and pulpectomy

Exclusion criteria:

History of systemic diseases Allergy to dental anesthesia Any phobias from injections and dental work Having abscess and toothache at the injection site

Age

From **7 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **28**

More than 1 sample in each individual

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

In each person, the two half-jaws are randomly assigned to the case (cold) and control (gel) groups. Injection in cold group after using ice cream and in control group after using benzocaine gel 20%, each for 1 minute, with lidocaine 2% anesthesia and epinephrine 1 / 100,000 with needle with 30 gauge length 16 mm will be performed by the same operator.

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

It should be noted that the samples are divided into two groups, in half of them, the first injection after the use of the topical anesthetic gel and the second injection after pre-cooling, and in the second group, vice versa. The anesthetic injection is performed by the first practitioner (pediatric dentist) who is only aware of the treatment group of the study. Then, second actors (pediatric dentistry and dentistry student) who are blind to the surface anesthesia selected during the study, will examine the child's behavior when injected with SEM scale (sound, eye and motor). And match the resulting data. At the end of each of the injections, the child is asked to rate the amount of pain felt on the Wonge-Baker scale.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran Islamic Azad University of Dental Branch of Medical Sciences

Street address

No. 4, Tenth Neyestan, Pasdaran Ave, Tehran

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Province

Tehran

Postal code

19585/175

Approval date

2018-04-22, 1397/02/02

Ethics committee reference number

IR.IAU.DENTAL.REC.1397,7

Health conditions studied

1

Description of health condition studied

Correlation of Pre-Cooling and Topical Anesthetic Gel on the pain perception of pediatric patients during palatal injection

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Determination of pain induced by injection in the case and control groups by the Wonge-Baker Faces pain rating scale

Timepoint

At the end of each of the injections, the child is asked to rate the amount of pain felt on the Wonge-Baker scale

Method of measurement

Image of Wonge-Baker Faces Pain Rating Scale

2

Description
Determination of pain induced by injection in the case and control groups by Sound-Eye-Motor behavioral evaluation scale
Timepoint
The pediatric dentist during the injection will examine the child's behavior with the SEM scale (sound, eyes and motion)
Method of measurement
Sound-Eye-Motor behavioral evaluation scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group: In half of the specimens, the injection is made after placing the impregnated cotton gel, prime gel (Banzocaine 20%) of the prime Dental Company of the United States for 1 minute in the anesthetic region.
Category
Treatment - Drugs

2

Description
Intervention group: In half of the samples, freezing of the carpool (which will be prepared by emptying the lidocaine cartridge and filling it with water and placing it in the freezer), will be used for 1 minute before injection.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Pediatrics section of Dental Branch of Tehran Islamic Azad University
Full name of responsible person
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Sponsors / Funding sources

1

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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
Islamic Azad University
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Will be announced at the end of the study.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable