

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation the effect of pre-cooling , topical anesthesia gel and placebo on the pain of palatal injection in children

Protocol summary

Study aim

Comparison of pain caused by palatal injection after using topical anesthetic gel, pre cooling, Vaseline and without any intervention

Design

Patients aged 7 to10 years who need to palatal injection of maxillary primary molar will be randomly selected and divided into 4 groups. In the group of topical anesthesia gel, injection after drying the tissue and placing benzoicin 20% gel for 1 minute, in pre cooling group, after drying and placing the ice carpool for 1minute. And in the placebo group, placing the Vaseline-impregnated ear cleaner for 1 minute, In the last injection group, no intervention will be performed. The injection will be given for 10 seconds, at a rate of 0.2 ml, at a distance of 5 mm from the free edge of the dental gums in the middle of the tooth by the same operator.SEM and Wong Baker Faces will be measured and recorded

Settings and conduct

Children 7to10 years old referring to the pediatrics department ofIslamic Azad University of Medical Sciences, Tehran2020, who need topalatal injection of maxillary primary teeth, randomly divided into 4 groups of 20% topical anesthetic gel, ice carpool, Vaseline befor injection

Participants/Inclusion and exclusion criteria

Inclusion:Co-operative children,Requiring bilateral palatal injection for routine dental work such as extraction, dental preparation,pulpotomy and pulpectomy
exclusion:History of systemic diseases,Allergy to dental anesthesia Any phobias from injections and dental work,Having abscess and toothache at the injection site

Intervention groups

In the first group: injection after tissue drying and use20% benzocaine gel for1 min,the second group by placing ice carpool for 1minute,in third group by placing Vaseline-impregnated ear cleaner in place for1 min,and in the fourth group, injections will be performed without any intervention

Main outcome variables

The rate of pain caused by injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180519039722N3**

Registration date: **2020-06-11, 1399/03/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-11, 1399/03/22**

Update count: **0**

Registration date

2020-06-11, 1399/03/22

Registrant information

Name

Saba Aghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2276 3459

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-09, 1399/03/20

Expected recruitment end date

2020-12-10, 1399/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of pre-cooling , topical anesthesia gel and placebo on the pain of palatal injection in children

Public title

Evaluation the effect of pre cooling , topical anesthesia gel on the pain of palatal injection in children

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 stainless steel crown (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

No information

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be randomly divided into 4 groups using Balanced block randomization using quadratic blocks using Randomization software.(Balanced block randomization)

Blinding (investigator's opinion)

Single blinded

Blinding description

Anesthesia will be injected by the first surgeon (pediatric dentist) using an anesthetic. The second practitioner, who is blind to the selected topical anesthetic and has been present since the start of the injection, will examine the child's behavior during the SEM (sound, eye, and motor) scale. At the end of each injection, the child is asked to rate the amount of pain felt by selecting a face based on the Wong-Baker Faces scale.

Placebo

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.9, Ninth Neyestan, Pasdaran Ave, Tehran

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2020-02-01, 1398/11/12

Ethics committee reference number

IR.IAU.DENTAL.REC.1398.067

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

Evaluation the effect of pre-cooling , topical anesthesia gel and placebo on the pain of palatal injection in children

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

Determination of pain

Timepoint

Immediately after the end of each injection, the child is asked to rate the amount of pain felt

Method of measurement

Image of Wonge-Baker Faces Pain Rating Scale

2**Description**

Determination of pain

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

Intervention group: In the topical anesthesia gel group, the injection will be performed for 1 minute after drying the tissue with a cotton swab and applying ear cleaner impregnated with 20% prime gel of benzocaine 20% topical anesthesia gel

Category

Treatment - Drugs

2

Description

Intervention group: Injection in the pre cooling group, after drying the tissue with cotton and placing ice carpool for 1 minute (to prepare the ice packs, lidocaine cartridges are emptied and filled with water and then placed in the freezer Took)

Category

Treatment - Other

3

Description

Intervention group: In the placebo group, after drying the tissue with a cotton swab and placing a vaseline for 1 minute at the injection site.

Category

Placebo

4

Description

Control group: The injection will be given alone and without any intervention

Category

N/A

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

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

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

Name of organization / entity

Islamic Azad University

Full name of responsible person

Taban Ahadi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available