Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of pre – cooling and topical anesthetic in pain perception Maxillary injection among pediatric

Protocol summary

Study aim

Comparison of pre cooling and topical anesthetic in pain perception maxillary injection among pediatric

Design

This study will be conducted as a double-blind,split-mouth phase 3 clinical trial.The number of samples in each group is 25 and a total of 50.Each half jaw is randomly assigned to the case (cold) or control (gel) group.The tool for collecting observations in this research is a standard SEM and Wang-baker-face questionnaire to measure pain intensity.

Settings and conduct

Injections and dental work on both sides are done in one session,in the children's department of the Faculty of Dentistry,Ilam University of Medical Sciences.After drying the tissue with cotton, 20% benzocaine gel will be used on one side and ice pack on the other side,each for 1 minute.Anesthesia injection will be performed by the first operator(pediatric dentist)using 2% lidocaine anesthetic and 1/100,000 epinephrine through a 27-gauge needle.The second operator,who is blinded to the selected surface anesthetic for the study,will examine the child's behavior during the injection with the child's voice,eye and movement scale.Also,at the end of each injection,the child is asked to rate the amount of pain felt based on the Wange-Baker scale.

Participants/Inclusion and exclusion criteria

The conditions for entering the study include no history of systemic diseases and any phobia of injections and dental work and allergy to anesthetics,no abscess and pain in the injected tooth,cooperation of the child and the need for two injections.The buccal side will be used for routine dental work such as extraction and etc,to close the raber dam.

Intervention groups

Intervention group:use of cold by ice carpool,which will be prepared by emptying the lidocaine cartridge and filling it with water and placing it in the freezer.Control group:use of benzocaine gel 20%

Main outcome variables

The amount of pain caused by the injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230718058840N1**
Registration date: **2023-08-20, 1402/05/29**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-20, 1402/05/29**
Update count: **0**

Registration date

2023-08-20, 1402/05/29

Registrant information

Name

Mohammadreza Miri

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-18, 1402/05/27

Expected recruitment end date

2023-09-18, 1402/06/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of pre – cooling and topical anesthetic in pain perception Maxillary injection among pediatric

Public title
Comparison of pre – cooling and topical anesthetic in pain perception Maxillary injection among pediatric
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Child cooperation 7 to 10 years Children who need injections on both sides of the buccal for routine dental work such as extraction, pulpotomy, etc.
Exclusion criteria:
History of systemic diseases sensitivity to anesthesia any phobia of injection and dental work having an abscess and pain in the injected tooth
Age
From **7 years** old to **10 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **50**
More than 1 sample in each individual
Number of samples in each individual: **2**
In each person, two half-jaws are randomly placed in two groups: case (cold) and control (gel). Injection in the cold group after using ice carpool and in the control group after using 20% benzocaine gel, each for 1 minute. It is performed with 2% lidocaine anesthesia and 1/100,000 epinephrine by the same operator using a 27-gauge needle with a length of 16 mm.
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 which the first injection is performed after applying the numbing gel and the second injection is performed after cold application, and in the second group, the opposite is done. Anesthesia injection will be performed by the first operator (pediatric dentist), who is the only person who knows about the treatment group of the study. Then, a second operator (a pediatric dentist and a dental student) who are blinded to the surface anesthesia chosen for the study, checks the child's behavior during the injection with the SEM (Child Voice, Eye and Movement) scale. and compare the obtained data with each other. Also, at the end of each injection, the child is asked to rate the level of pain felt based 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 Faculty of Dentistry, Ilam University of Medical Sciences
Street address
Banganjab - Research Boulevard - Ilam University of Medical Sciences campus
City
Ilam
Province
Ilam
Postal code
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Approval date
2023-07-17, 1402/04/26
Ethics committee reference number
IR.MEDILAM.REC.1402.097

Health conditions studied

1

Description of health condition studied
Cold and surface anesthetic gel on pain level caused by buccal injection in children
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Determining the amount of pain caused by injection in the study and control groups by the Wonge-Baker Faces evaluation scale
Timepoint
At the end of each injection, the child is asked to rate the amount of pain felt based on the Wonge-Baker scale.
Method of measurement
Image of the Wong-Baker Faces pain rating scale

2

Description
Determining the amount of pain caused by injection in the case group and the control group with SEM (voice,

eye and movement) behavioral assessment scale.

Timepoint

The pediatric dentist will examine the child's behavior during the injection with the voice-eye-movement scale

Method of measurement

SEM behavioral assessment scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In half of the samples, injection, after placing cotton dipped in benzocaine 20% anesthetic gel (prime gel) manufactured by American Prime Dental Company for 1 minute in the anesthesia area; will be done

Category

Treatment - Drugs

2

Description

Intervention group: In the other half of the samples, ice 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

Children's Department, Faculty of Dentistry, Ilam University of Medical Sciences

Full name of responsible person

Shirin Marzoughi

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Ilam University of Medical Sciences, Campus 2, Research Blvd, Banganjab, Ilam

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Sponsors / Funding sources

1

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Grant name

Ilam University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Ilam 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

Ilam University of Medical Sciences

Full name of responsible person

Mohammadreza Miri

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)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
It 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