

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

A Comparison study of the effects of Caine P with topical benzocaine in reducing needle insertion pain in Palatal anesthesia in children 9 to 12 years

Protocol summary

Study aim

Specific goals 1- Determining the mean Visual Analogue Scale (VAS) after the needle insertion in the benzocaine group 2- Determining the mean VAS after the needle insertion in the Caine P group 3- Comparison of VAS means after needle insertion in benzocaine and Caine P group

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 23 patients. Randomization will be done with Random allocation software.

Settings and conduct

The intervention is performed during 2 sessions. The Visual analog scale will be explained to the patient before starting. The desired areas will be dried with air for 5 seconds. With a cotton swab benzocaine will be applied, and in the next session, with the same preparation on the other side, Caine P will be applied. (The test is double-blind, and the patient and the dentist do not know which anesthesia was applied on which side.) 5 minutes after local anesthesia, the injection will be given for palatal anesthesia. After the injection, VAS scale is shown to the patient to rate their pain

Participants/Inclusion and exclusion criteria

Inclusion criteria include children who: 1- They are 9 to 12 years old. 2- They need to inject palatal anesthesia on both sides of the jaw. 3- Written consent was obtained from their parents. 4- They are cooperative. 5- They are systemically healthy. Exclusion criteria included children who: 1- With dissatisfaction and termination of cooperation. 2- Has an underlying disease such as allergies to anesthesia, epilepsy, asthma, etc. 3- At the age of less than 9 years or more than 12 years.

Intervention groups

Intervention group: Patients receiving Caine P as local anesthesia before palatal anesthesia injection Control

group: Patients receiving benzocaine as local anesthesia before palatal anesthesia injection

Main outcome variables

Needle entry pain before palatal anesthesia injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220412054516N1**

Registration date: **2022-05-08, 1401/02/18**

Registration timing: **prospective**

Last update: **2022-05-08, 1401/02/18**

Update count: **0**

Registration date

2022-05-08, 1401/02/18

Registrant information

Name

Mostafa Akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3370 0429

Email address

mostafa.akbari@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Comparison study of the effects of Caine P with topical benzocaine in reducing needle insertion pain in Palatal anesthesia in children 9 to 12 years

Public title
Comparison of the effect of Caine P with topical benzocaine on reducing needle entry pain in palatal anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Children 9 to 12 years Children who need palatal anesthesia injections on both sides of the jaw Written consent was obtained from their parents They are cooperative They are systemically healthy

Exclusion criteria:
At risk for Methemoglobinemia Allergic to benzocaine, lidocaine and prilocaine

Age
From **9 years** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **23**
More than 1 sample in each individual
Number of samples in each individual: **2**
One quadrant receiving the intervention (Caine P) and one quadrant receiving the control (benzocaine)

Randomization (investigator's opinion)
Randomized

Randomization description
After selecting the samples with inclusion criteria and without exclusion criteria, the quadrants were divided into two groups by blocking method. Randomization was performed with Random allocation software. Based on this, 23 double blocks were created with the mentioned software and provided to the main executor.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient and the dentist performing the treatment do not know which anesthesia was applied on which side.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandran University of Medical Sciences

Street address

Deputy of Research and Technology, Moallem Square, Sari

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2022-01-12, 1400/10/22

Ethics committee reference number

IR.MAZUMS.REC.1400.638

Health conditions studied

1

Description of health condition studied

Needle entry pain before palatal anesthesia injection

ICD-10 code

Y65.8

ICD-10 code description

Other specified misadventures during surgical and medical care

Primary outcomes

1

Description

Pain after needle insertion before palatal anesthesia injection

Timepoint

5 minutes after applying the local anesthetic cream

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: quadrant receiving Caine P as local anesthesia before injection = with a cotton swab on one side of the jaw Caine P (2.5% lidocaine cream and 2.5%

perilocaine similar to EMLA, product of IranNajo) will be applied by the injector. Injection will be done 5 minutes after local anesthesia with 2% lidocaine (manufactured by Daru Pakhsh) with a 30 gauge needle (manufactured by DENJECT) in a 3 mm area of the free gingival margin and that the needle's bevel is facing the bone, and the needle goes inside the tissue till it is in contact with bone. The injection is given to achieve palatal anesthesia. After the injection, the VAS scale is shown to the patient to indicate the amount of pain. Measurements with the VAS will be performed only once per session. The average of these numbers will be recorded and the data will be analyzed.

Category

Treatment - Drugs

2

Description

Control group: quadrant receiving Benzocaine as local anesthesia before injection = with a cotton swab on one side of the jaw benzocaine (20% benzocaine gel from Master dent) will be applied by the injector. Injection will be done 5 minutes after local anesthesia with 2% lidocaine (manufactured by Daru Pakhsh) with a 30 gauge needle (manufactured by DENJECT) in a 3 mm area of the free gingival margin and that the needle's bevel is facing the bone, and the needle goes inside the tissue till it is in contact with bone. The injection is given to achieve palatal anesthesia. After the injection, the VAS scale is shown to the patient to indicate the amount of pain. Measurements with the VAS will be performed only once per session. The average of these numbers will be recorded and the data will be analyzed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Touba Dental Clinic

Full name of responsible person

Doctor Abbas Mesgrani

Street address

Touba Dental Clinic, Khazar Square, Sari

City

Sari

Province

Mazandaran

Postal code

-

Phone

+98 11 3324 0003

Email

name@domain.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Pedram Ebrahimnejad

Street address

The headquarters of Mazandaran University of Medical Sciences, Beginning of Valiasr Highway, Imam Square, Sari

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Phone

+98 11 3304 4000

Email

ravabetoomi@mazums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Mehdi Taghian

Position

Assistant Professor and Faculty Member of Mazandaran University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Office Unit 610, 6th Floor, Shahriar 3 Building, Farhang St, Sari

City

Sari

Province

Mazandaran

Postal code

-

Phone

+98 11 3330 5443

Email

m.taghian@mazums.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Mehdi Taghian

Position

Assistant Professor and Faculty Member of
Mazandaran University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Office Unit 610, 6th Floor, Shahriar 3 Building,
Farhang St, Sari

City

Sari

Province

Mazandaran

Postal code

-

Phone

+98 11 3330 5443

Email

m.taghian@mazums.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Mostafa Akbari

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Rose Gold, Golestan 2 Ave, Farahabad Blvd, Sari

City

Sari

Province

Mazandaran

Postal code

4816996744

Phone

+98 11 3370 0429

Email

mostafa.akbari@mazums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

Part of the data, such as information about the main outcome or the like, can be shared

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Study documents will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

The use of data to carry out new research projects is permitted

From where data/document is obtainable

To the e-mail address of the respondent, Mostafa Akbari:
mostafa.akbari@mazums.ac.ir

What processes are involved for a request to access data/document

After reviewing the incoming emails, the data will be sent to the applicant.

Comments