

# 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

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##### Province

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##### Postal code

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+98 11 3304 4000

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ravabetomoomi@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

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## Person responsible for scientific inquiries

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Mehdi Taghian

**Position**

Assistant Professor and Faculty Member of  
Mazandaran University of Medical Sciences

**Latest degree**

Specialist

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## 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

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**Province**

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**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**