

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Comparison of the Effect of Benzocaine Gel(%20) and Lidocaine Spray(%10) on the Anesthesia of Maxillary First Molars Palatal Mucosa

#### Protocol summary

##### Summary

Injection is among dentistry a function that causes negative responses in children and hence .the reducing of injection pain due to that is one of the important problems in pediatric dentistry. The existing solution is, preparing the patient psychologically. Using some anti stress drugs and applying topical anesthesia before the injection. Topical anesthesia is one of the most important solutions before the injection. The attempt in this article compared two types of topical anesthetic agents; namely benzocaine gel (%20) and lidocaine spray (%10) in reducing the pain needle insertion in maxillary first molars palatal mucosa. Material and methods: in this clinical experimental study, 50 dental student who where physically fit and had no specific systemic diseases or drug sensitivity are select. The applicability of VAS was first are describe to every one of them and then benzocaine gel (%20) was supposedly use on the maxillary first molars palatal mucosa on one side, it use according to the manufactures instructions, needle of gauge 27 enter to the tissue .but no anesthetic agent is inject. After one minute, lidocaine spray (%10) applies to the other side of maxillary first molars palatal mucosa, it use according to its manufacturer's instructions. The needle of gauge 27 enter to the tissue but no anesthetic agent is inject .the selected individuals announced their rate pain due to using the gel and the spray in the selected individuals announce their rate pain due to using the gel and the spray. In accordance with VAS, the data was statistically analyzed by t-student test with the safety coefficient of %95.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013030512710N1**

Registration date: **2013-05-29, 1392/03/08**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-05-29, 1392/03/08

##### Registrant information

###### Name

Zeinab Jafary

###### Name of organization / entity

Dental University of Khorasgan

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1778 2855

###### Email address

z.jafari@khuisf.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Private

##### Expected recruitment start date

2013-05-30, 1392/03/09

##### Expected recruitment end date

2013-06-30, 1392/04/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the Effect of Benzocaine Gel(%20) and Lidocaine Spray(%10) on the Anesthesia of Maxillary First Molars Palatal Mucosa

##### Public title

Comparison of the Effect of gel and spray in anesthesia of palatal mucosa

##### Purpose

Supportive

### **Inclusion/Exclusion criteria**

Inclusion criteria: dental student who where phisically fit and had no specific systemic diseases or drug sensevity.

### **Age**

From **20 years** old to **26 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **50**

### **Randomization (investigator's opinion)**

N/A

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Islamic Azad University Khorasgan Ethics Committee

##### **Street address**

Khurasgan

##### **City**

Isfahan

##### **Postal code**

#### **Approval date**

2010-09-04, 1389/06/13

#### **Ethics committee reference number**

89061307001

## **Health conditions studied**

### 1

#### **Description of health condition studied**

local anesthesia

#### **ICD-10 code**

Y48.3

#### **ICD-10 code description**

## **Primary outcomes**

### 1

#### **Description**

pain

#### **Timepoint**

after intrvention

#### **Method of measurement**

visual analog scale

## **Secondary outcomes**

### 1

#### **Description**

patient cooperation

#### **Timepoint**

after intervention

#### **Method of measurement**

visual

## **Intervention groups**

### 1

#### **Description**

use of Benzocaine Gel(%20) ,needel of gauge 27 entered to the tissue but no anasthetic agent was injected .

#### **Category**

Diagnosis

### 2

#### **Description**

use of Lidocaine Spray(%10) \\needel of gauge 27 entered to the tissue but no anasthetic agent was injected

#### **Category**

Diagnosis

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Dental faculty of Islamic Azad University of Khorasgan

##### **Full name of responsible person**

##### **Street address**

Dental school, Islamic Azad University of Khorasgan, argavanieh boulevard, Khorasgan ,Isfahan

##### **City**

Isfahan

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Dental Faculty of Islamic Azad University Khorasgan, Isfahan

##### **Full name of responsible person**

Lale Samadpoor

**Street address**

Dental school, Islamic Azad University of  
Khorasgan, Arghavanieh boulevard, Khorasgan, Isfahan

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Dental Faculty of Islamic Azad University Khorasgan,  
Isfahan

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Dental Faculty of Islamic Azad University Khorasgan,  
Isfahan

**Full name of responsible person**

Zeinab Jafary

**Position**

Resident of pediatric dentistry

**Other areas of specialty/work**

**Street address**

Dental school, Islamic Azad University of Khorasgan,  
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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Dental Faculty of Islamic Azad University Khorasgan

**Full name of responsible person**

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**Position**

Resident of pediatric dentistry

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Islamic Azad University of Khorasgan

**Full name of responsible person**

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## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*