

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparison of the effect of local pressure and topical anesthesia with lidocaine/ prilocaine cream (EMLA) on pain during infiltration of maxillary canine teeth: Randomized clinical trial

#### Protocol summary

##### Summary

Study aim : to compare the effect of local pressure and topical anesthesia with lidocaine / prilocaine cream (EMLA) on pain during infiltration of maxillary canine teeth. Study design : clinical trial, randomized, triple blind, controlled with placebo, single center, phase 3 of trial. Table of random numbers is used for randomization in this study. Target population of the study : volunteer dental students educating at different grades. Main inclusion criteria: intact or with minimal caries and restoration maxillary canine teeth with normal view in periapical radiography and exclusion criteria is the patients with tooth pain at the time of study. Sample size is 140(35 per group). Interventions of this study: Group 1: Before administration of anesthesia, finger pressure would be applied on the alveolar mucosa at injection site in one side (experimental side). The finger pressure will be applied on the tooth crown in opposite side (control side). Group 2: Before administration of anesthesia, 5% EMLA cream would be applied on the injection site(experimental side). Placebo will be applied in the opposite side(control side).Group3: Before administration of anesthesia, finger pressure would be applied on the alveolar mucosa at injection site on one side and on the opposite side 5% EMLA cream would be used. Group 4: Before administration of anesthesia, 5% EMLA cream would be applied on the injection site and on the opposite side 20% benzocaine gel would be used. Primary outcome: Pain intensity (visual analogue scale)

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015120925456N1**

Registration date: **2016-03-03, 1394/12/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-03-03, 1394/12/13

##### Registrant information

###### Name

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###### Name of organization / entity

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##### Recruitment status

###### Recruitment complete

##### Funding source

Dental and Periodontal Research Center, Dental Faculty of Tabriz University of Medical Science

##### Expected recruitment start date

2015-10-18, 1394/07/26

##### Expected recruitment end date

2016-01-20, 1394/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of local pressure and topical anesthesia with lidocaine/ prilocaine cream (EMLA) on pain during infiltration of maxillary canine teeth:

Randomized clinical trial

### Public title

Comparison of the effect of local pressure and topical anesthesia with lidocaine /prilocaine cream (EMLA) on pain during infiltration of maxillary canine teeth:  
Randomized clinical trial

### Purpose

Other

### Inclusion/Exclusion criteria

Inclusion criteria: Healthy adults with the age 18-55 years old; intact or with minimal caries and restoration maxillary canine teeth with normal view in periapical radiography; normal probing depth; no sensitivity to palpation and percussion; no consumption of painkillers,analgesics and anxiolytics drugs in recent 2 weeks; no allergy to anesthetic material and no medical history; clinical diagnosis of intact tooth would be confirmed by response to electric pulp tester(PARKELL,PT-20,made in USA) and normal response(short momentary answer). Exclusion criteria: Systemic disease and/or maxillary sinusitis; patients with tooth pain at the time of study; unstable heart disease; allergy to anesthesia material of lidocaine 2% with 1/80000 epinephrine or latex or lidocaine or prilocaine gels; facial or oral parasthesia; consumption of painkillers,analgesics and anxiolytics drugs in 2 weeks before treatment; presence of periapical radiolucency; pregnancy; breast-feeding; non-repairable tooth and presence of crown

### Age

From **18 years** old to **55 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **140**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Triple blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

### Street address

Daneshgah Avenue, Tabriz University of Medical Sciences, Tabriz

### City

Tabriz

### Postal code

### Approval date

2015-10-18, 1394/07/26

### Ethics committee reference number

TBZMED.REC.1394.600, letter number:5/4/7721

## Health conditions studied

### 1

#### Description of health condition studied

local anesthesia

#### ICD-10 code

XXII

#### ICD-10 code description

Codes for special purposes

## Primary outcomes

### 1

#### Description

pain intensity

#### Timepoint

immediately after injection

#### Method of measurement

visual analoge scale

## Secondary outcomes

### 1

#### Description

Hematoma

#### Timepoint

24 hours after treatment

#### Method of measurement

visual observation(objective)

## Intervention groups

### 1

#### Description

This is a split mouth, randomized clinical trial study. Intervention group 1: Before administration of anesthesia, finger pressure would be applied on the alveolar mucosa at injection site in one side.

#### Category

Treatment - Drugs

### 2

#### Description

In the opposite side of intervention group 1, finger pressure will be applied on the tooth crown.

**Category**

Placebo

**3****Description**

Intervention group 2: Before administration of anesthesia, 5% EMLA cream would be applied on the injection site(experimental side).

**Category**

Treatment - Drugs

**4****Description**

In the opposite side of intervention group 2, placebo will be applied at the injection site.

**Category**

Placebo

**5****Description**

Intervention group3: Before administration of anesthesia, finger pressure would be applied on the alveolar mucosa at injection site on one side and on the opposite side 5% EMLA cream would be used.

**Category**

Treatment - Drugs

**6****Description**

Intervention group 4: Before administration of anesthesia, 5% EMLA cream would be applied on the injection site and on the opposite side 20% benzocaine gel would be used.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Department of Operative Dentistry of Dental faculty

**Full name of responsible person**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Dental and Periodontal Research Center

**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?**

Yes

**Title of funding source**

Dental and Periodontal Research Center

**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**

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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*