

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison anesthetic onset and duration of Citanest and Dentanest in maxillary and mandibullary molars with normal pulps.

#### Protocol summary

##### Summary

Objectives : Maxillary Buccal Infiltration and Inferior Alveolar Nerve Block(IANB) are the most common techniques to achieve anesthesia for routine dental procedures of maxillary and mandibular teeth ,respectively . Prilocaine is one of the anesthetic solution which specially practical in some systemic diseases. There are two commercial types of Prilocaine naming Citanest and Dentanest . The aim of this study was to compare the anesthetic efficacy of these two solutions regarding the onset and duration . Design: This study designed randomized cross-over clinical trial. Setting and Conduct : Maxillary Buccal Infiltration and IANB were applied by one trained practitioner and the onset and duration of pulpal and soft tissue anesthesia were measured using EPT and Pin Prick ,respectively every 2minutes for a period of 60 minutes . Subjects with no sign of lip anesthesia 20min after receiving IANB were excluded from the study. The obtained data were analyzed using T-test and Wilcoxon test. Participants including major eligibility criteria : In this study participated 20 healthy subjects which had maxillary and mandibular molars with no caries , large restorations , crowns and periodontal diseases . They written informed consent was obtained from each subject. Intervention : Age , Needle gauge , tooth type , periodontal disease , Injection duration . Measures variables : Onset of pulpal anesthesia in maxillary buccal infiltration , pulpal duration of maxillary buccal infiltration , onset of pulp in IANB , pulpal duration of IANB .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015102319207N2**

Registration date: **2016-01-25, 1394/11/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-01-25, 1394/11/05

##### Registrant information

###### Name

Bahareh Dadresanfar

###### Name of organization / entity

Islamic Azad university of dentistry

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

investigator

##### Expected recruitment start date

2014-03-20, 1392/12/29

##### Expected recruitment end date

2015-03-20, 1393/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison anesthetic onset and duration of Citanest and Dentanest in maxillary and mandibullary molars with normal pulps.

##### Public title

Comparison citanest and dentanest

##### Purpose

Other

## **Inclusion/Exclusion criteria**

Inclusion criteria : Subjects between 18 to 65 yrs ; had not any systemic disease ; they had not used any medication ; had not sensitivity to anesthesia solution ; had not pathology in injection area ; had fist or second maxillary and mandibular molars Exclusion criteria : Caries and crown and periodontal disease in studied molars ; pregnancy ; systemic disease

## **Age**

From **18 years** old to **65 years** old

## **Gender**

Both

## **Phase**

2-3

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **20**

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

Randomized

## **Randomization description**

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

Double blinded

## **Blinding description**

## **Placebo**

Not used

## **Assignment**

Parallel

## **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

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

Ethics committee of Islamic Azad University of Dentistry tehran branch

##### **Street address**

10th Neyestan , Pasdaran

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2014-02-25, 1392/12/06

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

پ/320/د

## **Health conditions studied**

### 1

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

onset and duration of pulpal anesthesia

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

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

## **Primary outcomes**

### 1

#### **Description**

Onset of Pulp and Soft tissue anesthesia

#### **Timepoint**

Per 2-minute post injection

#### **Method of measurement**

Electric Pulp Tester ( EPT ) , Pin Prick

## **Secondary outcomes**

### 1

#### **Description**

Duration of Pulp and Soft tissue anesthesia

#### **Timepoint**

Every 2- minute post injection

#### **Method of measurement**

Electric Pulp Tester , Pin prick

## **Intervention groups**

### 1

#### **Description**

Intervention:1.8ml ( one cartridge ) Dentanest( Perilocaine 3% with 0/03 flypersine) once during 30 to 60 seconds in Maxillary buccal infiltratin and Inferior Alveolar Nerve Block.

#### **Category**

N/A

### 2

#### **Description**

Control group : 1.8 ml (one cartridge ) Citanest (Perilicaine 3 % with 0/03 flypersin ) once during 30 to 60 seconds in Maxillary Buccal Infiltration and Inferior Alveolar Nerve Block .

#### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Islamic Azad University, Dental Branch of Tehran , Endodontics department

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

Dr. Pooneh Mohebbi

##### **Street address**

10th Neyestan , Pasdaran

##### **City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Azad university of dentistry

**Full name of responsible person**

Dr. Pooneh Mohebbi

**Street address**

Endodontics Department, 10th Neyestan, Pasdaran ave

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Azad university of dentistry

**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**

Islamic Azad University - Dental Branch

**Full name of responsible person**

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**Position**

Assistant Professor

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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*