

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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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 first 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 infiltration 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

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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

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**

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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