

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

Dr.Mehdi Daneshpooy, Assistant Professor, Operative Dentistry specialist

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Second floor, Entry 3, Dental Faculty, Daneshgah Avenue, Tabriz

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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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Second floor, Entry number 2, Tabriz dental faculty, Daneshgah Avenue, Tabriz

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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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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