

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Comparative Study of the Amount of Pain from Palatal Injection Immediately and with a Delay Following Buccal Infiltrate Injection with Two Anesthetic Agents, Lidocain and Articain in Patients Requiring Restorative Treatment of Maxillary Premolar Teeth

Protocol summary

Summary

Our goal is to compare the amount of pain from immediate and delayed palatal injection following buccal infiltrate injection. In this randomized triple blinded, clinical trial, 92 patients referring to the dental school of Kermanshah University of Medical Sciences will be chosen. Inclusion criteria: People of 18 to 50 years of age, needing restorative treatment of maxillary premolar teeth. Exclusion criteria: use of sedatives and anti-depressant medications during two weeks prior to the injection. Patients are randomly divided into two groups of 46. Buccal injection will be performed using lidocain in one group and articaine in the other group; while palatal injection will be performed using lidocain in both groups. For each patient, injections will be performed twice with an interval of two weeks. Once, the palatal injection will be randomly performed immediately after the buccal injection, while the other time, it will be performed with a 10 minute delay. During the buccal injection, 1.8 milliliters of anesthetic agent, during 60 seconds, at 3 to 4mm penetration depth at the maxillary premolar vestibule will be delivered by the first operator, and during the palatal injection 0.3 milliliters will be delivered during 10 seconds, and 1cm far from the marginal gingiva of premolar teeth, at 3 to 4mm penetration depth by the second operator. The extent of pain from injection will be measured after buccal and palatal injections using the Visual Analogue Scale of pain. Palatal injection will be delivered by the second operator who will not be present in the room during the buccal injection. A dark tape will cover each anesthetic cartridge.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071817880N4**

Registration date: **2017-02-21, 1395/12/03**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-02-21, 1395/12/03

Registrant information

Name

Roohollah Sharifi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-02-25, 1395/12/07

Expected recruitment end date

2017-03-18, 1395/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparative Study of the Amount of Pain from Palatal Injection Immediately and with a Delay Following Buccal Infiltrate Injection with Two Anesthetic Agents, Lidocain and Articain in Patients Requiring Restorative Treatment of Maxillary Premolar Teeth

Public title

The Comparison of the amount of pain from immediate and delayed palatal injection following buccal infiltrate injection using two anesthetic drugs

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: people with ages of 18 to 50 years and in good health; needing restorative treatment of maxillary premolar teeth. Exclusion criteria: the use of anesthetic drugs and sedatives and antidepressants during two weeks before the injection; allergic reactions to local anesthetic; edentulous at the premolar region of maxilla; medical history of cardiovascular and kidney diseases; any active pathology at the injection site; gastrointestinal bleeding or ulceration; pregnant and nursing patients.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Randomized using sealed envelopes

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Ethics Committee of Kermanshah University of Medical Sciences, Shahid Beheshti Blvd

City

Kermanshah

Postal code

67146673159

Approval date

2016-07-13, 1395/04/23

Ethics committee reference number

KUMS.REC.1395.261

Health conditions studied

1

Description of health condition studied

Local anaesthetics

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes

1

Description

The intensity of pain

Timepoint

Immediately after the buccal and palatal injection

Method of measurement

Based on the Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Palatal injection of lidocain 2% with Epinephrine 1:80000, 10 min after buccal injection of articain 4% with Epinephrine 1:100000

Category

Treatment - Other

2

Description

Intervention group 2: Palatal injection of lidocain 2% with Epinephrine 1:80000, 10 min after buccal injection of lidocain 2% with Epinephrine 1:80000

Category

Treatment - Other

3

Description

Control group 1: Palatal injection of lidocain 2% with Epinephrine 1:80000, immediately after buccal injection of articain 4% with Epinephrine 1:100000

Category

Treatment - Other

empty

4

Description

Control group 2: Palatal injection of lidocain 2% with Epinephrine 1:80000, immediately after buccal injection of lidocain 2% with Epinephrine 1:80000

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Endodontic, School of Dentistry, Kermanshah University of Medical Sciences.

Full name of responsible person

Dr Roohollah Sharifi

Street address

Shariati st.,

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Kourosh Hamzei

Street address

Building No.2, Shahid Beheshti Boulevard, Vice Chancellor for Research, Kermanshah University of Medical Sciences

City

Kermanshah

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, Kermanshah University of Medical Sciences

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

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah Dentistry School

Full name of responsible person

Maryam FarAra

Position

Dental student

Other areas of specialty/work

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Person responsible for updating data

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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