Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Nov 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

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Roohollah Sharifi
Name of organization / entity
Kermanshah University of Medical Sciences
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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

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 Medial Sciences.
Full name of responsible person
Dr Roohollah Sharifi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences
Full name of responsible person
Kourosh Hamzeei
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Building No.2, Shahid Beheshti Boulverd, Vice Chancellor for Research, Kermafnshah 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
empty

Person responsible for general inquiries

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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