Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Premedication effect of Ketorolac infiltration injection on post endodontic pain

Protocol summary

Summary

Objective: The aim of this study is to evaluate premedication with ketorolac infiltration on post endodontic pain in patients with symptomatic irreversible pulpitis. Design: Randomized double blind clinical trial Setting and conduct: Sixty adult volunteers with including criteria will be divided into two groups (n=30) based on random table. All patients will receive standard inferior alveolar nerve block of 2% lidocaine with 1:800000 epinephrine and supplemental buccal infiltration of 0.9 mL 2% lidocaine with 1:800000 epinephrine. After five minutes one group will receive supplemental buccal infiltration of 30 mg/mL of Ketorolac Tromethamine and the control group will receive buccal infiltration of normal saline. Endodontic access preparation will initiate after 15 minutes of initial IANB with two negative responses to the electric pulp test. Endodontic treatment of all the patients will be performed in a single visit, using crown down method and with rotary instrumentation till master apical file size# 30.06. The pain level will be immediately recorded after the treatment and at the 2,4,6 and 24 hours following the Ketorolac infiltration using Heft- Parker Visual Analog Scale (HP- VAS). Data will be evaluated using Repeated measured test (if possible) and otherwise non-parametric tests such as rival Friedman and X2 test. SPSS version 22 will be used for data analysis .Participants including major eligibility criteria: all patients age ranged 18-65 with symptomatic irreversible pulpitis (HP VAS ≥54) of a mandibular molar tooth who need root canal treatment and are without systemic diseases; nonsmoking;non pregnant, non breat feeding without any medicine consumption or analgesic and sedation Intervention: Ketorolac infiltration Main outcome measures : Pain level at immediately after the treatment, 2,4,6 and 24 hours following the root canal treatment using HP VAS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061316845N6**
Registration date: **2016-09-25, 1395/07/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-09-25, 1395/07/04

Registrant information

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Nahid Akhlaghi
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research ,Dental Branch Tehran Islamic Azad University

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Premedication effect of Ketorolac infiltration injection on post endodontic pain

Public title
Premedication effect of an anti inflammatory analgesic on post root canal treatment pain
Purpose
Prevention
Inclusion/Exclusion criteria
patients with age ranged 18-65; without systemic diseases ; without any medicine consumption; nonsmoking; non pregnant; non breast feeding; with symptomatic irreversible pulpitis (Visual Analog Scale ≥ 54) in one mandibular molar who need root canal therapy
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: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double 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 Islamic Azad University, Tehran dental Branch
Street address
10th Neyestan, Pasdaran Ave
City
Tehran
Postal code
18468
Approval date
2016-06-20, 1395/03/31
Ethics committee reference number
ir.iau.rec.1395.190

Health conditions studied

1

Description of health condition studied
Post endodontic Pain
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain after root canal treatment
Timepoint
Immediately after the treatment and at the 2,4,6 and 24 hour intervals
Method of measurement
Pain rate based on analgesic demand and VAS

Secondary outcomes

empty

Intervention groups

1

Description
Injection of Ketorolac infiltration
Category
Treatment - Drugs

2

Description
Injection of normal saline infiltration
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Post grad Endodontic Department, Dental Branch, Tehran Islamic Azad University
Full name of responsible person
Mahsa Azarshab
Street address
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Vice Chancellor of Research ,Dental Branch Islamic Azad University

Full name of responsible person
Arash azizi

Street address
no 4, 10th Neyestan, Pasdaran Ave.

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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 of Research ,Dental Branch Islamic Azad University

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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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