

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 $\geq$ 54) of a mandibular molar tooth who need root canal treatment and are without systemic diseases; nonsmoking;non pregnant, non breast 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

Name

Nahid Akhlaghi

Name of organization / entity

Tehran Dental Branch Islamic Azad University

Country

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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 $\geq$ 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