

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Efficacy of Ketorolac infiltration on success rate of inferior alveolar nerve block in patients with irreversible pulpitis: A randomized double blinded clinical trial

Protocol summary

Summary

Objectives: The aim of this study is to examine whether combining an intraoral injection of a non steroidal anti-inflammatory drug (Ketorolac), in association with conventional inferior alveolar nerve block, would improve the success rate in teeth with irreversible pulpitis.

Design: Randomized double blind clinical trial
Setting and conduct: Forty adult volunteers will randomly divide into two groups (n=20). All patients will receive standard infra alveolar nerve block of 4% Articaine with 1:100000 epinephrine and supplemental buccal infiltration of 0.9 mL 4% Articaine with 1:100000 epinephrine. After five minutes one group will receive supplemental buccal infiltration of 30 mg/mL of Ketorolac Tromethamine and other 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. Pain during dentin, access cavity preparation and root canal instrumentation will be recorded using VAS. The success is considered as none or mild pain during treatment. The data will be analyzed using Mann-U-Whitney and chi-squared tests.

Participants including major eligibility criteria: all patients with symptomatic irreversible pulpitis (Heft Parker visual analogue scale ≥ 54) of a mandibular molar tooth without systemic diseases; non smoking; without any medicine consumption or analgesic and sedation Intervention: Ketorolac infiltration
Main outcome measures : Pain during dentin removal , access cavity preparation and root canal instrumentation using visual analyzing scale

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042616845N2**

Registration date: **2015-07-07, 1394/04/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-07-07, 1394/04/16

Registrant information

Name

Nahid Akhlaghi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-03-01, 1393/12/10

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Ketorolac infiltration on success rate of inferior alveolar nerve block in patients with irreversible

pulpitis: A randomized double blinded clinical trial

Public title

Efficacy of Ketorolac on success rate of dental anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:patients with age ranged 18-65; without systemic diseases ; without any medicine consumption; non smoking; non pregnant; non breast feeding; with symptomatic irreversible pulpitis (Visual Analog Scale \geq 54) in one mandibular molar that needs root canal therapy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Approval date

2014-09-28, 1393/07/06

Ethics committee reference number

P/212/D

Health conditions studied

1

Description of health condition studied

symptomatic irreversible pulpitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anesthesia following the injection

Timepoint

5 Minutes

Method of measurement

Electric pulp tester

Secondary outcomes

1

Description

Root Canal treatment without pain

Timepoint

15 minutes following buccal infiltration

Method of measurement

Pain rate based on VAS

Intervention groups

1

Description

Injection of Ketorolac infiltration

Category

Treatment - Drugs

2

Description

Injection of placebo infiltration

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University Tehran Dental Branch

Full name of responsible person

Dr Nahid Mohammadzadeh Akhlaghi

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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

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no 4, 10th neyestan

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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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Web page address**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