Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 قشفث 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

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Tehran Dental Branch Islamic Azad University

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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 ≥ 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
Street address
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

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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