

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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  $\geq 54$ ) 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 **فنشفت** 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

Tehran Dental Branch Islamic Azad University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2201 1751

###### Email address

n\_akhlaghi@dentaliau.ac.ir

##### 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

##### Street address

10th Neyestan, Pasdaran Ave

##### City

Tehran

## 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

**City**

Tehran

**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**

Islamic Azad University Tehran Dental Branch

**Full name of responsible person**

Dr Nahid Mohammadzadeh Akhlaghi

**Position**

Associate Professor /DDS,MS

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+98 21 2201 1932

**Email**

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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*