

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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

Iran (Islamic Republic of)

##### Phone

+98 21 2201 1751

##### Email address

n\_akhlaghi@dentaliau.ac.ir

##### 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

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, Pasdaran Ave.

**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**

Dental Branch, Tehran Islamic azad University

**Full name of responsible person**

Nahid Mohammadzadeh Akhlaghi

**Position**

Associate Professor /DDS, MS

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**Fax**

**Email**

**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*