

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Efficacy of ketorolac and lidocaine inferior alveolar nerve blocks in patients with with symptomatic irreversible pulpitis: a prospective double blind, randomized clinical trial

#### Protocol summary

##### Study aim

The aim of this study is to determine if inferior alveolar nerve block of ketorolac and lidocaine would improve the success of anesthesia in teeth with symptomatic irreversible Pulpitis

##### Design

Sixty healthy volunteer adults with including criteria will be randomly divided into two case and control groups (n=30) using computer software and each patient will receive the own sealed envelop.

##### Settings and conduct

This study will be done in the Endodontic department, dental school, Islamic Azad University of medical sciences. Based on computer software, the patients will be divided into two groups and each of the patients will receive his/her own envelop which includes the details of that group. The envelopes have the same shape and a person out of the study based on computer randomization will number them, so the evaluator and the assessor are unaware about them.

##### Participants/Inclusion and exclusion criteria

patients with age ranged 18-65; without systemic diseases; without any medicine consumption; non smoking; non allergic to NSAID or anesthetic solution; non pregnant; non breast feeding; with symptomatic irreversible pulpitis (Visual Analog Scale  $\geq$  54) in one mandibular molar that needs root canal treatment; undrestanding the data and consent forms and accepting to participate at the research.

##### Intervention groups

All patients will receive standard inferior alveolar nerve block (IANB) injection with 1.8 ml 2% lidocaine 2% containing 1:100000 epinephrine following negative aspiration. After 5 minutes, the patients of case group will receive another standard IANB injection with 1 ml ketorolac tromethamin 30 mg/ml. The patients of control group will receive a second IANB with sham injection.

##### Main outcome variables

Pain level evaluation at different stages of root canal therapy

#### General information

##### Reason for update

##### Acronym

IANB

##### IRCT registration information

IRCT registration number: **IRCT20140305016845N7**

Registration date: **2018-01-16, 1396/10/26**

Registration timing: **prospective**

Last update: **2018-01-16, 1396/10/26**

Update count: **0**

##### Registration date

2018-01-16, 1396/10/26

##### 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

##### Expected recruitment start date

2018-02-14, 1396/11/25

##### Expected recruitment end date

2018-12-31, 1397/10/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Efficacy of ketorolac and lidocaine inferior alveolar nerve blocks in patients with with symptomatic irreversible pulpitis: a prospective double blind, randomized clinical trial

**Public title**

Efficacy of block injection of an anti inflammatory medicine in patients with mandibular dental pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

patients with age ranged 18-65 without systemic diseases without any medicine consumption 8 h perior root canal treatment symptomatic irreversible pulpitis (HP-Visual Analog Scale(VAS)  $\geq$  54) in one mandibular molar that needs root canal treatment understanding of consent form and VAS accepting to participate in research

**Exclusion criteria:**

Patients under 18 and above 65 years old systemic diseases smoking/drug patients pregnant/breast feeding Allergy to NSAID/ anesthetic solutions without a molar tooth no symptomatic irreversible pulpits HP-VAS under 54 Inability to understand data and VAS forms not accepting to participate in the study

**Age**

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

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

computer software will be used for randomization, then sealed envelopes for the patients

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The participant, data collector (Dental student), principle investigator ( Dental faculty Professor and the data assessor are blind to the

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Dental school, Islamic Azad University of Medical Sciences, Tehran Iran

**Street address**

No 9, 9th Neyestan, Pasdaran Street

**City**

Tehran

**Province**

Tehran

**Postal code**

19468

**Approval date**

2017-11-14, 1396/08/23

**Ethics committee reference number**

IR.IAU.DENTAL.REC.1396,31

**Health conditions studied****1****Description of health condition studied**

symptomatic irreversible pulpits

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

pain level during root canal treatment based on HP-VAS 170 mm.

**Timepoint**

Caries and dentin removal, access preparation and root canal preparation stages

**Method of measurement**

Heft-Parker Visual Analog Scale( HP-VAS) 170 mm

**Secondary outcomes****1****Description**

Decreasing the pain level

**Timepoint**

pain level at caries/dentin removal, access cavity preparation and root canal preparation procedures

**Method of measurement**

Heft-Parker visual analog scale ( 170 mm)

## Intervention groups

1

### Description

Intervention group: 1 mL of Ketrolac Tromethamine solution (30 mg/mL) ( Exir co, Boroojerd, Iran) will be entered to empty carpoul of lidocaine and will be injected at the first IANB site as second block.

### Category

Treatment - Drugs

2

### Description

Control group: In the control group, 5 minutes following the first inferior alveolar nerve block(IANB) using lidocaine, the sham injection will be rendered. So a syringe including 1 mL of lidocaine will enter closely to the first IANB site without injection, so the patient thinks the injection will be provided for him/her.

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Endodontic department, dental school, Tehran Islamic Azad University of medical sciences

#### Full name of responsible person

Nahid Mohammadzadeh Akhlaghi

#### Street address

No 9, 9th Neyestan

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#### Phone

+98 21 2201 1751

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akhlaghinahid@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Islamic Azad University

#### Full name of responsible person

Arash Azizi

#### Street address

no9, 9th Neyestan

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#### Phone

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#### Email

aziziaa@hotmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Islamic Azad University

#### Proportion provided by this source

100

#### Public or private sector

Private

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Islamic Azad University

#### Full name of responsible person

Nahid Mohammadzadeh Akhlaghi

#### Position

Associate Professor

#### Latest degree

Master

#### Other areas of specialty/work

Dentistry

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Islamic Azad University

#### Full name of responsible person

Nahid Mohammadzadeh Akhlaghi

#### Position

Associate Professor

#### Latest degree

Specialist  
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## Person responsible for updating data

### Contact

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Dr Nahid Mohammadzadeh Akhlaghi  
**Position**  
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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Undecided - It is not yet known if there will be a plan to make this available  
**Study Protocol**  
Undecided - It is not yet known if there will be a plan to make this available  
**Statistical Analysis Plan**  
Undecided - It is not yet known if there will be a plan to make this available  
**Informed Consent Form**  
Undecided - It is not yet known if there will be a plan to make this available  
**Clinical Study Report**  
Undecided - It is not yet known if there will be a plan to make this available  
**Analytic Code**  
Undecided - It is not yet known if there will be a plan to make this available  
**Data Dictionary**  
Undecided - It is not yet known if there will be a plan to make this available