

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

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 updating data

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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