Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 alergic to NSAID or anesthetic solution; non pregnant; non breast feeding; with symptomatic irreversible pulpitis (Visual Analog Scale ≥ 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) ≥ 54) in one mandibular molar that needs root canal treatment underestanding 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 commitee 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
City
Tehran
Province
Tehran
Postal code
19468
Phone
+98 21 2201 1751
Email
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
City
Tehran
Province
Tehran
Postal code
19468
Phone
+98 21 2276 3446
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
Street address
No 9, 9th Neyestan, Pasdaran street
City
Tehran
Province
Tehran
Postal code
19468
Phone
+98 21 2201 1751
Email
akhlaghinahid@yahoo.com

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
Other areas of specialty/work
Dentistry
Street address
No 9, 9th Neyestan, Pasdaran Street
City
Tehran
Province
Tehran
Postal code
19468
Phone
+98 21 2259 8224
Email
akhlaghinahid@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr Nahid Mohammadzadeh Akhlaghi
Position
Associate Professor /DDS,MS
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
No 9, 9th Neyestan, Pasdaran street
City
Tehran
Province
Tehran
Postal code
19468
Phone
+98 21 2201 1751
Fax
Email
akhlaghinahid@yahoo.com
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