

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparative Evaluation of the effect of lidocaine-ketorolac mixture and lidocaine on Inferior Alveolar Nerve Block anesthesia in patients with irreversible pulpitis

Protocol summary

Study aim

Patients pain management is a challenging factor in Endodontics. Appropriate managing of this pain can build a positive attitude among the patients. Studies have shown, if the amount of inflammatory factors reduces, the anesthesia success rate will be increased and the pain level will be decreased. Ketorolac is of the NSAIDs that has strong analgesic effect. The purpose of this study is to peruse lidocaine-ketorolac mixture effect on the success of inferior alveolar nerve block during the root canal treatment in patients who have Irreversible Pulpitis.

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment.

Settings and conduct

The changed anesthetic cartridge will be coded and will be given to the endodontist. Finally, the root canal treatment procedure will be started while the dentist and the patient don't know the composition of anesthetic liquid.

Participants/Inclusion and exclusion criteria

Main inclusion criteria is symptomatic Irreversible pulpitis in lower molar teeth. The pain level should be more than 54 on Heft-Parker's index; Pregnancy, digestive disease and ASA III or IV are the most important factors for excluding patients from the study.

Intervention groups

Patients who involved in control group will be injected a conventional lidocaine 2% with epinephrin 1/100000 and another cartridge which 0.8 ml of that has been brought out and filled by normal saline; The patients who involved in intervention group will be recieved two injections too. The first injection consists of conventional lidocaine 2% with epinephrin 1/100000 and the second injection has 0.8 ml of ketorolac 30mg/ml instead of lidocaine.

Main outcome variables

Finding better solution for managing the pain in patients who suffer from irreversible pulpitis; Improving patients attitude to dental procedures.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181104041542N1**

Registration date: **2019-01-18, 1397/10/28**

Registration timing: **prospective**

Last update: **2019-01-18, 1397/10/28**

Update count: **0**

Registration date

2019-01-18, 1397/10/28

Registrant information

Name

Hessamoddin Faghihian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3651 6128

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-01, 1397/11/12

Expected recruitment end date

2019-04-18, 1398/01/29

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative Evaluation of the effect of lidocaine-ketorolac mixture and lidocaine on Inferior Alveolar Nerve Block anesthesia in patients with irreversible pulpitis

Public title
Comparison of the Effectiveness of Lidocaine and Lidocaine-Ketorolac Mixture on Mandible Anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients Suffered from Irreversible Pulpitis in Their Lower Mandibular Molars Patients should be Considered ASA I or II
Exclusion criteria:
 Patients who are nursing or lactating during the study
 patients suffered from mental or physical disability
 patients who are allergic to NSAIDs patients who are using medicine during the study

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are Selected by Convenience Sampling and Disturbed into Case and Control Group by Random Numbers

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, conventional and changed anesthetic cartridge will be divided and numbered to two groups by an operator. The cartridges will be given to researcher. The researcher who doesn't know type of the cartridges will give them to dentist who wants to do the research. Finally by the permission of patients the research will be done.

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Building No. 4, Isfahan University of Medical Sciences, Hezar Jarib St

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8174673461

Approval date

2018-10-24, 1397/08/02

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.285

Health conditions studied

1

Description of health condition studied

Irreversible Pulpitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mandibular Molar Pain

Timepoint

Prior to intervention and After anesthetic injection during root canal treatment

Method of measurement

Heft-Parker's Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After informed consent, the initial anesthetic substance which is lidocaine HCL 2% with epinephrine 1:100,000, will be injected. After that, the studied anesthetic substance (0.8 mL of lidocaine HCL 2% with epinephrine 1:100,000 + 1ml of Ketorolac 30mg/ml) will be injected. Root canal treatment will have

started after numbness of lower lip. The patient has been instructed to report the pain on the index if he/she feels any pain.

Category

Treatment - Drugs

2

Description

Control group: On this group, the second injection has normal saline instead of Ketorolac. Other steps are the same as intervention group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Clinic of Isfahan University of Medical Sciences

Full name of responsible person

Abbasali Khademi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

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

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

Esfahan University of Medical Sciences

Full name of responsible person

Hessomoddin Faghihian

Position

Dental Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Reyhaneh Faghihian

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Individual patients data after unidentification and the information of the main outcome is available.

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Researchers working in academic institutions and research centers related to dentistry

Under which criteria data/document could be used

Access to data and documentation is for study purposes only and is not subject to change or analysis

From where data/document is obtainable

Vice-Chancellor's Office for Research, Isfahan Dentistry School

What processes are involved for a request to access data/document

Initially, the relevant scientific evidence and the reasons for the need for data will be provided to the Office of the Vice-Chancellor of Research and after the documents are presented, they will decide.

Comments