Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

The comparison of three oral prophylactic drugs on success of inferior alveolar nerve block and post operative pain in patient with symptomatic irreversible pulpitis.

Protocol summary

Study aim

The aim of this study was to compare the efficacy of three oral anesthetics (Ibuprofen, Naproxen and Ketrolac) in the success of inferior alveolar nerve block and post operative pain in patients with irreversible symptomatic pulpitis referred to the department of Endodontics, Azad University Islamic of Tehran will be held in 1397.

Design

Pragmatic, community based, parallel group, double blind, randomized controlled trial

Settings and conduct

This clinical trial is double blind (all drugs and the control group are prepared in the same manner and the evaluator is different from the prescriber of the drug). It is randomized (blocked) and controlled by the placebo.80 healthy patients were selected from patients referring to the Department of Endodontics, Islamic Azad University of Tehran, who required root canal treatment of 1st or 2ed mandibular molars with irreversible pulpitis. Patients with moderate to severe pain are included in the study. The pain level of these teeth before the root canal therapy is evaluated by a cold test and EPT based on the HP-VAS measurement criterion of more than 54. Patients are divided into four groups according to the randomized table: the first group received 500 mg of Naproxen, the second group received 10 mg Ketrolac, and the third group received 400 mg of ibuprofen and the oral control placebo group are prescribed. After an hour, anesthetizing is done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-symptomatic irreversible pulpitis 2-Healthy participant 3-First & second molar of mandible Exclusion criteria: 1-Systematic disease 2-Pregnancy and lactation 3-Taking analgesics in the last 12 hours 4-Allergic drugs 5-History of RCT 6-Periodontitis & PDL widening more than 1mm

Intervention groups

Group 1: Naproxen 500 mg, Group 2: Ketrolac 10 mg, Group 3: Ibuprofen 400 mg, Control group: Placebo

Main outcome variables

Pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181021041405N1**
Registration date: **2019-03-28, 1398/01/08**
Registration timing: **retrospective**

Last update: **2019-03-28, 1398/01/08**
Update count: **0**

Registration date

2019-03-28, 1398/01/08

Registrant information

Name

Hadi Labbaf ghassemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2240 0996

Email address

labbaf@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-06, 1397/09/15

Expected recruitment end date

2019-02-04, 1397/11/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison of three oral prophylactic drugs on success of inferior alveolar nerve block and post operative pain in patient with symptomatic irreversible pulpitis.

Public title
Effect of Naproxen and Ketrolac on local anesthesia and post operative pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
symptomatic irreversible pulpitis Healthy participant First & second molar of mandible People between 18 and 65 years old
Exclusion criteria:
Systematic disease Pregnancy and lactation Taking analgesics in the last 12 hours Allergic drugs History of RCT Periodontitis & PDL widening more than 1mm
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The block randomization method is used to divide the subject into subgroups called blocks, then the individuals in each block are randomly assigned to treatment conditions. In this type of sampling, each member of the defined community There is an equal and independent chance to be present in the sample, meaning that independence is not the choice of a member in any way in choosing other members of the community. In this method, first we get the list of all the members, then we assign a score to each of them and use the random number table to select the required number. In the random numbers table, the random numbers of the randomly assigned drugs are categorized in each group. The randomization unit in this study is individual. To avoid the bias, cryptographic selection is used to prevent selected bias. In this study, for the patient to be blind, the capsules that are in shape, color, size, and weight are each other and the same as those of the placebo group, are used to both patient and patient of the contents of the capsules. Treatment applied and taken bias does not exist.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double blind clinical trial. In this study, patients are blinded to practitioners of capsules that are in shape, color, size, and weight of each other and are similar to those of the placebo group, so that both the patient and the patient do not know the content of the capsules. Then, from the random numbers table, we put the drugs in different groups, and the four drugs are coded by the person not in the research, and the codes are not determined until the end of the study. So far, each drug has a code that is unknown to the patient and the content of the capsule, but the person outside the study knows that each code is the drug. After this stage, the assessor and, with the corresponding code, will be evaluated and analyzed. Their statistics. In the end, after obtaining information about each code and its alignment with drugs, information on the effects of each drug is identified. 1. researcher who prescribes drugs is blinded to the case & placebo medications due to all medications are encapsulated in identical size & shape capsules. 2. Patient is also blinded due to who does not know about the containing capsules. 3. outcome assessor is the main researcher who does not know about the prescribed medications. 4. statistician is absolutely blinded to prescription and assessment.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran Medical science Branch, Islamic Azad university
Street address
No. 4, Neyestan 9 Alley, Pasdaran Street
City
Tehran
Province
Tehran
Postal code
19858175
Approval date
2018-04-22, 1397/02/02
Ethics committee reference number
IR.IAU.DENTAL.REC.1397.035

Health conditions studied

1

Description of health condition studied
Local anesthesia in Root canal therapy and post Root canal therapy pain
ICD-10 code
K04.0
ICD-10 code description
Pulpitis

Primary outcomes

1

Description
Pain severity
Timepoint
Measurement of pain severity before intervention, after access cavity preparation, after pulpotomy, pulpectomy and 6, 12, 24, 48, 72 hours after finish the intervention
Method of measurement
Heft Parker visual analog scale(VAS) (0_170 mm)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Naproxen 500 mg, non steroidal anti-inflammatory drugs prescribe 1 hour before intervention.
Category
Treatment - Drugs

2

Description
Intervention group 2: Ketrolac 10 mg, non steroidal anti-inflammatory drugs prescribe 1 hour before intervention.
Category
Treatment - Drugs

3

Description
Intervention group 3: ibuprofen 400 mg, non steroidal anti-inflammatory drugs prescribe 1 hour before intervention.
Category
Treatment - Drugs

4

Description
Control group: The placebo, which is color and shape and weight, is the same as the original medicine and contains a small amount of glucose that is given 1 hour before the start of the intervention.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran dental branch, Islamic Azad University
Full name of responsible person
Peyman Mehrvarz far
Street address
No.4, Neyestan 9 Alley, Pasdaran Street.
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Province
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Phone
+98 21 2256 4570
Email
p_mehrvarzfar@dentaliau.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Arash Azizi
Street address
No.4, Neyestan 9 Alley, Pasdaran Street
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Postal code
19585175
Phone
+98 21 2256 4571
Email
a_azizi@dentaliau.ac.ir
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
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

Islamic Azad University

Full name of responsible person

Peyman Mehrvarzfar

Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

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Islamic Azad University

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only some part of data including age, gender, and post operative pain intensity would be shared

When the data will become available and for how long

6 mount after publication

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Academic dental teams can request documentation in collaboration with project researchers through the above mentioned communication paths.

From where data/document is obtainable

Peyman Mehrvarzfar. contract Call 09194889838 and email p_mehrvarzfar@dentaliau.ac.ir

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

Written letter from the organ and educational and scientific institutes will be sent to the dental faculty of Islamic Azad University and will be sent to the competent authorities within 6 months after the approval of the competent authorities.

Comments