Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jul 2026

Efficacy of premedication with ibuprofen on the success of lower alveolar nerve block with lidocaine in comparison with infiltration of articaine in symptomatic irreversible pulpitis.

Protocol summary

Study aim

Finding a way to induce deep anesthesia in marked teeth with irreversible pulpitis

Design

In this triple blind randomized clinical trial, 88 patients referred to the Department of Endodontics, Faculty of Dentistry, Qazvin, with the first or second mandibular molars having the diagnose of irreversible pulpitis, randomly ,divided into four groups (22 patients in each group). For the purpose of blinding, a code is assigned to each group.

Settings and conduct

Patients referring to the faculty of dentistry of Qazvin University of Medical Sciences who have a history of spontaneous pain will be studied. pulpal vitality tests will be performed on the Intended tooth (Precusion test, electricl pulp test and Cold test). Patients are asked to determine their pain based on the Visual Analogue Scale (VAS). A 100-millimeter line is drawn and the patient is asked to show a degree of pain on it (patients with pain 66 and above will be included in the study.) Then written consent is received from all patients to participate in the research. None of the patients, the practitioner, and the statistician are aware of the contents of the capsules, and only the drug supplier is aware of the contents of the capsules. All capsules containing the drug or placebo have the same shape , color and size and have their own code. All injections are done by an endodontist. 15 minutes after both types of injection , the access cavity begins. In the group that received the IANB anesthesia, they are asked about their lips' anesthesia. In the group that received infiltration anesthesia,anesthetized soft tissue is checked with a explorer . If the pain is felt during the access cavity, the treatment process stops and the patient determines the degree of pain. In the event of a mild pain (21 mm or less) experienced by the patient, the anesthetic will be considered successful and otherwise anesthesia is considered unsuccessful and supplemental anesthetic injection will be performed. After completing pulpotomy, the patient is refereed to the general or specialized department to continue the treatment.

Participants/Inclusion and exclusion criteria

Lower mandibular molar with irreversible pulpitis

Intervention groups

In groups 2 and 4, placebo capsules, in groups 1 and 3, 400 mg ibuprofen capsules are given to patients.30 minutes after the administration of the drug, patients receive anesthesia related to their group.Patients in the lidocaine group,received 1.8 mL of 2% lidocaine with epinephrine 1.100000 (Daroupakhsh, Iran) using standard block and Patients in the articaine group receive 1.8 ml of articaine 4% with Epinephrine 1.100000 (DeraPakhsh, Iran) by buccal infiltration.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131216015814N3**
Registration date: **2018-02-21, 1396/12/02**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-21, 1396/12/02**
Update count: **0**

Registration date

2018-02-21, 1396/12/02

Registrant information

Name

Shahrzad Jalali

Name of organization / entity

Qazvin University Of Medical Sciences

Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source
Private

Expected recruitment start date
2017-11-22, 1396/09/01
Expected recruitment end date
2018-04-04, 1397/01/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of premedication with ibuprofen on the success of lower alveolar nerve block with lidocaine in comparison with infiltration of articaine in symptomatic irreversible pulpitis.

Public title
The effect of premedication on tooth anesthesia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with first or second mandibular molars requiring root canal treatment with the diagnosis of symptomatic irreversible pulpitis and a history of spontaneous pain. Patients who are completely healthy or have a mild systemic disease that is well controlled (ASA I, II) Patients who have the ability to fill out a questionnaire and a consent letter Patients over 18 years old
Exclusion criteria:
Patients with heart pacemakers Asthma, coagulation disorders, immune deficiency, diabetes, hypertension, mental disorders pregnancy Sensitivity or contraindication for receiving lidocaine, articaine, epinephrine and NSAIDs The presence of open apex or calcification in the root of the Intended tooth The presence of extensive restoration or periodontal disease use of analgesic drugs 12 hours before treatment
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
From patients with symptomatic irreversible pulpitis referring to the Department of Endodontics, Faculty of Dentistry Qazvin, 88 patients will be randomly selected on the basis of win pepi software.
Blinding (investigator's opinion)
Triple blinded
Blinding description
None of the patients, the practitioner, and the statistician are aware of the contents of the capsules, and only the manufacturer of the drug is aware of the contents of the capsules. All capsules containing the drug or placebo have the same shape and color and size and have their own code. In Group 1 and 2 placebo capsules, and in groups 3 and 4, ibuprofen 400 mg capsules are given to the patients.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences
Street address
Faculty of Dentistry Qazvin,Shahid Bahonar Blvd., Qazvin
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Qazvin
Province
Qazvin
Postal code
3415759811
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
IR.QUMS.REC.1396.122

Health conditions studied

1

Description of health condition studied
Irreversible pulpitis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain during cavity preparation
Timepoint
Fifteen minutes after injection
Method of measurement
Visual analogue scale

Secondary outcomes

1

Description
Need for complementary injection
Timepoint
Fifteen minutes after block injection
Method of measurement
Complementary anesthetizing

Intervention groups

1

Description
Intervention 1:Premedication with ibuprofen (400 mg) 30 minutes before anesthesia and infiltration of articaine 4% + epinephrine 1.100000
Category
Treatment - Drugs

2

Description
Intervention 2: Premedication with placebo 30 minutes before anesthesia and infiltration of articaine 4% + epinephrine 1.100000
Category
Placebo

3

Description
Intervention group: Intervention 3: Premedication with ibuprofen (400 mg) 30 minutes before anesthesia and IANB anesthesia with lidocaine 2% + epinephrine 1.100000
Category
Treatment - Drugs

4

Description
Intervention 4: Premedication with placebo 30 minutes before anesthesia and IANB anesthesia with lidocaine 2% + epinephrine 1.100000
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Endodontics, Faculty of Dentistry, Qazvin University of Medical Sciences
Full name of responsible person
Shahrzad Jalali
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
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Bakhtiari Tina
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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
Qazvin University of Medical Sciences
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
Qazvin Dental School

Full name of responsible person
Shahrzad Jalali

Position
Endodontist/ Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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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
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
All the information of the participants

When the data will become available and for how long
Up to one year after the publication of the results

To whom data/document is available
Free access to data for all people

Under which criteria data/document could be used
Data will be available for designing further studies and meta-analyzes

From where data/document is obtainable
To communicate with Ramezani masoumeh Mobile number:09129490407
Email:M269_ramezani@yahoo.com

What processes are involved for a request to access data/document
Up to 2 weeks

Comments