Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A Comparison of the effect of lidocaine, articaine and mepivacaine on pulpal anesthesia in maxillary molars with irreversible pulpitis (double-blind randomized trial)

Protocol summary

Study aim

Comparison of the effect of lidocaine, articaine and mepivacaine on pulpal anesthesia in maxillary molars with irreversible pulpitis Determining the percentage of anesthesia in the group receiving lidocaine, articaine and mepivacaine Comparison of anesthesia in groups receiving lidocaine, articaine and mepivacaine based on gender and age Determining the mean time of onset of anesthesia in lidocaine, articaine and mepivacaine groups Comparison of mean onset time of anesthesia of lidocaine, articaine and mepivacaine groups Comparison of cold response percentage in three groups of lidocaine, articaine and mepivacaine

Design

Double-blind clinical trial with 114 samples with three parallel and randomized groups with six permutation blocks

Settings and conduct

Due to the importance of creating deep anesthesia in dental treatments, this study will be performed in Guilan Dental School. In this study, 114 maxillary first or second molars in people with irreversible pulpitis were divided into three groups of 38 and each group was injected with one of three types of anesthesia: mepivacaine, lidocaine and articaine. After injection using an electronic pulp tester And the cold test is checked every two minutes for up to 10 minutes. The teeth that were anesthetized will be treated. If the painless treatment is successful, it will be classified as a success in creating anesthesia.

Participants/Inclusion and exclusion criteria

Patients over 16 years of age and under 65 years of age who have not had any systemic disease or have taken any medication, have not smoked without a history of allergy to anesthesia, have not taken painkillers within 24 hours, are not pregnant or breastfeeding.

Intervention groups

Lidocaine group Mepivacaine group Articaine Group

Main outcome variables

anesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220226054132N1**
Registration date: **2022-03-06, 1400/12/15**
Registration timing: **prospective**

Last update: **2022-03-06, 1400/12/15**
Update count: **0**

Registration date

2022-03-06, 1400/12/15

Registrant information

Name

Farhad Jamali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3340 2051

Email address

farhadja.a@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-02, 1401/01/13

Expected recruitment end date

2022-04-19, 1401/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison of the effect of lidocaine, articaine and mepivacaine on pulpal anesthesia in maxillary molars with irreversible pulpitis (double-blind randomized trial)

Public title

A Comparison of the effect of lidocaine, articaine and mepivacaine on pulpal anesthesia in maxillary molars with irreversible pulpitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

people must have irreversible pulpitis in maxillary molar

Exclusion criteria:

Age

From **16 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the block randomization method with 4 permutation blocks will be used. For this reason, considering that the study is double-blind and only analysts are aware of the study groups, considering the blind therapies A, B and C, the order of assigning treatment to individuals based on the time of their study will be as follows: (The complete randomization file is available as an Excel file. The randomization was done with SAS software version 9): Seed: 117257145755086 Block sizes: 6 Actual list length: 114 block identifier, block size, sequence within block, treatment • 1, 6, 1, Group C • 1, 6, 2, Group B • 1, 6, 3, Group C • 1, 6, 4, Group A • 1, 6, 5, Group A • 1, 6, 6, Group B • 2, 6, 1, Group B • 2, 6, 2, Group C

Blinding (investigator's opinion)

Double blinded

Blinding description

All patients are divided into three experimental groups by block randomized randomization. Patients are classified into four subgroups based on sex and tooth type (maxillary first or second molars). Patients in each subgroup are then randomly assigned to lidocaine, articaine, and mepivacaine groups using six blocks. Equal number of lidocaine and articaine and mepi-cocaine cartridges are prepared and given a code. To hide random allocation, a code-aware nurse randomly provides cartridges to clinicians based on groups (lidocaine, articaine, and mepivacaine). There is a code for each packed cartridge. One clinician fills out a questionnaire. And another clinician does the injections. All injections are performed by a clinician. This is a double-blind study, meaning that the clinician performing the injections, the patient, the person evaluating the outcome, and the statistician are not aware of the type of anesthetic

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Guilan University of Medical Sciences

Street address

No. 31, Professor Samiei Blvd., Fooman Shimi Complex

City

Rasht

Province

Guilan

Postal code

4484154179

Approval date

2022-02-24, 1400/12/05

Ethics committee reference number

IR.GUMS.REC.1400.591

Health conditions studied

1

Description of health condition studied

Irreversible pulpitis

ICD-10 code

B95

ICD-10 code description

Streptococcus, Staphylococcus, and Enterococcus as the cause of diseases classified elsewhere

Primary outcomes

1

Description

Answer to electronic pulp tester and cold test

Timepoint

2, 4, 6, 8 and 10 minutes

Method of measurement

Using the electronic pulp tester and increasing its degree from 0 to 8, if the tooth does not feel numb, and using a

cotton ball on which the cold spray is sprayed and the buccal side of the tooth is studied for up to 10 seconds.

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: lidocaine receiving group - the second intervention group: articaine receiving group - the third intervention group: mipivacaine receiving group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Guilan Faculty of Dentistry
Full name of responsible person
Farhad Jamali Afarmejani
Street address
No. 31, Professor Samiei Blvd., Fooman Shimi Complex
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Guilan Faculty of Dentistry
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Phone
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Email
dental@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht University of Medical Sciences
Proportion provided by this source
50
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
Rasht University of Medical Sciences
Full name of responsible person
Farhad Jamali
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available