Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of anesthetic efficacy of 2% lidocaine with 1/100000 epinephrine and 3% mepivacaine in premolars of maxilla with irreversible pulpitis

Protocol summary

Study aim
Comparison of the efficacy of 2% lidocaine anesthesia with epinephrine 1/ 100,000 and 3% mepivacaine in maxillary premolars with irreversible pulpitis

Design
Clinical trial with intervention and control group, prospective, randomized, double blinded, with a sample size of 76 patients

Settings and conduct
This study is done in a dental clinic. Before treatment, patients are given an explanation for the current research, and after receiving the necessary information, patients are given written consent for treatment. Patient treatment is done in a single session by a specific dentist. Encoding and giving anesthetic Carpools is done by one of the secretaries. After 7 minutes of injection of anesthetic solution, access to the endodontic cavity begins. Patient and the dentist are not aware of injactable solution. During accessing the endodontic cavity, the VAS chart is used to measure patient pain.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The presence of maxillary premolars with irreversible pulpitis, People aged 18 to 65 Exclusion criteria: We have to inject another anesthetic solution, Allergies to local anesthetics and sulfites, Pregnant women, Taking any medication 6 hours before referral, Having Systemic Disease

Intervention groups
Intervention group: 1.8 ml of 3% mipivacaine (Novocol Pharmaceutical of Canada Inc.) is injected with the infiltration technique to the maxillary premolars. Control group: 1.8 ml of 2% lidocaine with 1/100,000 epinephrine (Tehran Darou Pakhsh Pharmaceutical Mfg.Co.) is injected with the infiltration technique to the maxillary premolars.

Main outcome variables
Patient pain during treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180818040824N1**
Registration date: **2018-10-30, 1397/08/08**
Registration timing: **retrospective**

Last update: **2018-11-25, 1397/09/04**
Update count: **1**

Registration date
2018-10-30, 1397/08/08

Registrant information

Name
Saeide Jafari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-20, 1396/12/01

Expected recruitment end date
2018-07-21, 1397/04/30

Actual recruitment start date
2018-02-20, 1396/12/01

Actual recruitment end date
2018-07-21, 1397/04/30

Trial completion date
2018-08-05, 1397/05/14

Scientific title
Comparison of anesthetic efficacy of 2% lidocaine with 1/100000 epinephrine and 3% mepivacaine in premolars of maxilla with irreversible pulpitis

Public title
Comparison of anesthetic efficacy of 2% lidocaine and 3% mepivacaine in premolars of maxilla with irreversible pulpitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The presence of maxillary premolars with irreversible pulpitis People aged 18 to 65

Exclusion criteria:
We have to inject another anesthetic solution. Allergies to local anesthetics and sulfites Pregnant women Taking any medication 6 hours before referral Having Systemic Disease The widening of periodontal ligament space The presence of a periapical radiolucency

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **76**
Actual sample size reached: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
Those who have entered the study are randomly assigned to one of the two intervention and control groups in the random numbers table. Making random sequences is such that the even numbers and the odd numbers associated with the lidocaine group and the mepivacaine group respectively.

Blinding (investigator's opinion)
Double blinded

Blinding description
76 carpools (38 carpools containing 2% lidocaine with 1 /100,000 epinephrine and 38 carpools containing 3% mepivacaine) are covered with paper and the codes A and B are inserted on it. The purpose is that the patient and the dentist is not aware of anesthetized injections, encoding is done by one of the secretaries.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Yasouj University of Medical Sciences

Street address
No. 17, Subsidiary A, Imam Hossein Town

City
Yasuj

Province
Kohgilouyeh-va-Boyrahmad

Postal code
7591817719

Approval date
2018-01-06, 1396/10/16

Ethics committee reference number
IR.YUMS.REC.1396.152

Health conditions studied

1

Description of health condition studied
Anesthetizing the teeth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Patient pain during treatment

Timepoint
While providing access cavity

Method of measurement
Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Infusion of buccal infiltration one cartridge (1.8 ml) local 3% mepivacaine anesthetic solution, manufactured by the Canadian Novocol

Category
Treatment - Drugs

2

Description
Control group: Infusion of buccal infiltration one cartridge (1.8 ml) local anesthetic 2% Lidocaine with 1/100,000 epinephrine, manufactured by Tehran Darou pakhsh

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental Clinic
Full name of responsible person
Ali Barzin
Street address
Next to the Blood Transfusion Organization, Motahari Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj 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
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student
Latest degree
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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
No - There is not 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
Data include patient gender, patient age, patient pain

When the data will become available and for how long
After publishing the article

To whom data/document is available
Based on the University's discretion

Under which criteria data/document could be used
According to the conditions that the University determines

From where data/document is obtainable
Yasouj University of Medical Sciences, Research Deputy

What processes are involved for a request to access data/document
Communicating with University's research unit

Comments