

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 injectable 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% mepivacaine (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 Paksh 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

Kohgiluyeh-va-Boyer-Ahmad

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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Hossein Oryad

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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****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Saeide Jafari

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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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