# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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)

**Phone**
+98 71 5357 3693

**Email address**
mohammad.layegh@yums.ac.ir

**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
**City**
Yasuj
**Province**
Kohgilouyeh-va-Boyrahmad
**Postal code**
75919-54661
**Phone**
+98 74 3322 8274
**Email**
mohammad.layegh@yums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Yasouj University of Medical Sciences
**Full name of responsible person**
Hosein Oryad
**Street address**
Vice Chancellor for Research, Yasouj University of Medical Sciences, Motahhari Blvd
**City**
Yasuj
**Province**
Kohgilouyeh-va-Boyrahmad
**Postal code**
7481374129
**Phone**
+98 74 3334 6078
**Fax**
+98 74 3334 6079
**Email**
en@yums.ac.ir
**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
**Street address**
No. 17, Western Suburbs, Imam Hossein Town
**City**
Yasuj
**Province**
Kohgilouyeh-va-Boyrahmad
**Postal code**
7591817719
**Phone**
+98 74 3333 5199
**Email**
saeide.jafari73@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Yasouj University of Medical Sciences
**Full name of responsible person**
Mohammadkarim Layeghnezhad
**Position**
Faculty Dentist
**Latest degree**
Specialist
**Other areas of specialty/work**
Dentistry
**Street address**
Dr Layeghnezhad Dental Office, Hejrat 2nd Street, Ferdowsi Avenue
**City**
Yasuj
**Province**
Kohgilouyeh-va-Boyrahmad
**Postal code**
7591796987
**Phone**
+98 74 3322 4635
**Email**
mohammad.layegh@yahoo.com

## Person responsible for updating data

**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

**Street address**
No. 17, Shahid Fazli Alley, Imam Hossein Town

**City**
Yasuj

**Province**
Kohgilouyeh-va-Boyrahmad

**Postal code**
7591817719

**Phone**
+98 74 3333 5199

**Email**
saeide.jafari73@gmail.com

## 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**