

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Evaluation of synergism of prilocaine and lidocaine in local anesthesia in patients with irreversible pulpitis

#### Protocol summary

##### Study aim

The study of the synergistic effects of prilocaine and lidocaine on local anesthesia

##### Design

A total of 60 patients referred to the Department of Endodontics of Shahid Sadoughi Dental School in Yazd, who have a mandibular molar with an irreversible symptomatic pulpitis, are diagnosed with root canal therapy and are considered as systemic predisposing conditions for injectable solutions Periclas and lidocaine do not contain epinephrine. The number of patients was determined based on similar studies.

##### Settings and conduct

Shahid Sadoughi Faculty of Dentistry, Yazd

##### Participants/Inclusion and exclusion criteria

1. Mandibular molar teeth with irreversible pulpitis
2. The teeth can be repaired.
- 3- Apex toothpaste (age over 18)
4. Awareness is normal and can respond to vital tests.

##### Intervention groups

A group whose second numbness is prilocaine.

##### Main outcome variables

Local anesthesia depth

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190315043057N1**

Registration date: **2019-04-17, 1398/01/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-04-17, 1398/01/28**

Update count: **0**

##### Registration date

2019-04-17, 1398/01/28

##### Registrant information

##### Name

Jalil Modaresi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3625 5881

##### Email address

j.modaresi@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-08, 1398/01/19

##### Expected recruitment end date

2019-05-21, 1398/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of synergism of prilocaine and lidocaine in local anesthesia in patients with irreversible pulpitis

##### Public title

Evaluation of synergism of prilocaine and lidocaine in local anesthesia in patients with irreversible pulpitis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Mandibular molar teeth with irreversible pulpitis  
The teeth can be restorable  
Tooth apex is closed (age +18)  
The patient who has normal intelligence and are able to meet the critical tests

###### Exclusion criteria:

Patients with systemic problems that have a

contraindication for lower alveolar block injections, such as those with hemorrhagic problems A history of allergy to local anesthetics of dentistry Use of the medication 24 hours before local anesthetic injection Patients that have a contraindications for use of any of the drugs used in the study (epinephrine, lidocaine, prilocaïne) Disturbance in vital signs of the patient after local anesthetic injection Tooth with severe periodontal disease A teeth with sensitivity to percussion or has periapical pathological symptoms in radiography The absence of a healthy tooth or a teeth with small restoration on the opposite side as a control tooth During the study, patient dissatisfaction and announced withdrawal

### Age

From **18 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

N/A

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

After the first injection with lidocaine anesthesia, in the first patient, the second injection is done using the heads or tails method, One of the anesthetics of perylocaïne or lidocaine is chosen as second anesthetic solution. In all odd number sample cases, this anesthetic solution (perlucaïne or lidocaine) and for all cases with even number, other anesthetic solution are selected as the second anesthetic solution.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

National Ethics Committee for Biomedical Research

##### Street address

Bahonar Square- Shahid sadoghi medical university

central park

#### City

Yaz

#### Province

Yazd

#### Postal code

8916978477

#### Approval date

2018-11-04, 1397/08/13

#### Ethics committee reference number

IR.SSU.REC.1397.088

## Health conditions studied

### 1

#### Description of health condition studied

Irreversible Pulpitis

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

depth of local anesthesia

#### Timepoint

10 min after injection of local anesthesia

#### Method of measurement

Using pulse electric tester, cold test and patient response to the VAS chart

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The group whose second anesthesia is a Perilocaïne solution

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid sadoghi dental university

##### Full name of responsible person

Seyed jalil Modaresi

##### Street address

Shahid Sadoghi Square- Shahid Sadoghi dental university

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Yazd

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j.modaresi@ssu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Seyed Jalil Modaresi  
**Street address**  
Bahonar Suare- Shahi dadoghi Dental University  
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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**  
Yazd 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**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Seyed Jalil Modaresi  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dentistry

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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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**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available