

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 Periclast 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, prilocaine) 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 perylocaine or lidocaine is chosen as second anesthetic solution. In all odd number sample cases, this anesthetic solution (perlucaine 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 Perilocaine 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
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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 updating data

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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