

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of superficial anesthetic effect between the liposomal form of Lidocaine-Prilocaine and the emulsion form of Lidocaine-Prilocaine

Protocol summary

Study aim

Pain control is one of the most important subjects in dentistry and dentist goals. Many dental procedures show concomitant use of topical and superficial anesthetic has a significant role in reducing fear and anxiety. The lidocaine-Prilocaine solution as a topical anesthetic has many uses for reducing pain caused by needle injection, But it has a low analgesic effect. The purpose of this study is the creation and examination of a topical product with higher efficacy and durability on the mucosa on the superficial anesthesia of mucosa before injection rather than the soluble form.

Design

Among patients with chronic periodontitis that referred to the dental clinic who required bilaterally surgical flap with infiltration injection of an anesthetic in the posterior region of maxilla, 15 patients considering inclusion and exclusion criteria were randomly chosen.

Settings and conduct

After explaining the outline and getting consent and infiltration injection of an anesthetic in the vestibular zone of each of the first and second premolar teeth and first and second molar teeth of the maxilla, one of the eight anesthetics are randomly chosen. At the injection area of one side, four concentrations of topical anesthetics including Lidocaine-Prilocaine emulsion form 2%, 5%, 7.5%, and 10% are topically applied. On the other side of the maxilla, this work is repeated with the liposomal form. After two minutes the injection is done. Then, the pain of needle injection at each area was measured using the VAS scale. This research is done in the MUMS faculty of dentistry.

Participants/Inclusion and exclusion criteria

15 patients

Intervention groups

Applying anesthetic in two forms of emulsion and liposomal

Main outcome variables

Age, Sex, Intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210109049981N1**

Registration date: **2021-01-18, 1399/10/29**

Registration timing: **retrospective**

Last update: **2021-01-18, 1399/10/29**

Update count: **0**

Registration date

2021-01-18, 1399/10/29

Registrant information

Name

Mohammad Mahdi Javidan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 3650

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javidontist@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-14, 1398/07/22

Expected recruitment end date

2020-01-12, 1398/10/22

Actual recruitment start date

2019-10-14, 1398/07/22

Actual recruitment end date

2020-01-12, 1398/10/22

Trial completion date

2020-03-03, 1398/12/13

Scientific title

Comparison of superficial anesthetic effect between the liposomal form of Lidocaine-Prilocaine and the emulsion form of Lidocaine-Prilocaine

Public title

Comparison of anesthetic effect between the two forms of Lidocaine-Prilocaine

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who need flap surgery at the maxillary second molar site on both sides

Exclusion criteria:

Allergic to local anesthetics Anesthetic infiltration can not be done. Systemic diseases that are contraindicated for oral surgery NSAIDs and psychotropic medication usage

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **15**

Actual sample size reached: **15**

Randomization (investigator's opinion)

Randomized

Randomization description

-

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and Clinicians are blinded.

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad Medical Science University, faculty of dentistry

City

Mashhad

Province

Razavi Khorasan

Postal code

0123456789

Approval date

2018-03-03, 1396/12/12

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1397.054

Health conditions studied

1

Description of health condition studied

Patients who need flap surgery at the maxillary second molar site on both sides

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain intensity after local anesthetic injection

Timepoint

Pain intensity measurement will be done two minutes after injection in two sessions.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Rubbing the liposomal form or emulsion form of the anesthetic before applying local anesthetic at the second maxillary tooth area on one side

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad faculty of dentistry

Full name of responsible person

Nasser Sargolzaei

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Sponsors / Funding sources

1

Sponsor

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Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
No
Title of funding source
Mashhad University of Medical Sciences, Faculty of
Dentistry
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
Bojnourd University of Medical Sciences
Full name of responsible person
Mohammad Mahdi Javidan
Position
Dentistry Student
Latest degree

Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Fax**Email**

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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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

-

When the data will become available and for how long

Access is available via Mashhad University of Medical Sciences, faculty of dentistry.

To whom data/document is available

Researchers with affiliations

Under which criteria data/document could be used

-

From where data/document is obtainable

Mashhad University of Medical Sciences, faculty of dentistry

What processes are involved for a request to access data/document

-

Comments