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

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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
Street address
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
Nasser Sargolzaee
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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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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