Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of palatal mucosa anesthesia due to infiltration of lidocaine compared to articaine in the buccal region of maxilla

Protocol summary

Study aim

This study was designed to evaluate the effectiveness of buccal articaine anesthesia compared to lidocaine for achieving palatal anesthesia in Maxillary dental procedures.

Design

A double-blind, crossover clinical trial with a control group and an intervention group will be conducted on 34 patients.

Settings and conduct

The study was conducted at the School of Dentistry, Isfahan University of Medical Sciences, Iran, as a double-blind crossover clinical trial. Participants received buccal injections of both anesthetic agents, articaine and lidocaine, with a washout period observed between administrations. The choice of the initial anesthetic agent and the side of the maxilla for the first injection were randomized. Blinding was ensured by coloring the cartridges in two distinct shades (blue and red), so that both the operator and the patient remained unaware of the anesthetic being administered.

Participants/Inclusion and exclusion criteria

All candidates for bilateral Maxillary implants will be included in the study. Subjects should not have the following conditions: Age less than 18 years, History of trauma or nasal surgery, History of psychiatric disorder, Congenital anomalies, Peripheral neuropathy or presence of sensory deficits in the facial area prior to surgery, Uncontrolled systemic conditions

Intervention groups

Intervention group: Patients will receive 0.9 mL of articaine at the buccal sites of the maxillary canine and first molar. Control group: Patients will receive 0.9 mL of lidocaine at the same buccal sites of the maxillary canine and first molar. In both groups, the drug will be administered by injection using the infiltration technique.

Main outcome variables

Change in palatal mucosal sensory and pain threshold after buccal anesthetic injection.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131205015665N8**
Registration date: **2025-09-05, 1404/06/14**
Registration timing: **prospective**

Last update: **2025-09-05, 1404/06/14**
Update count: **0**

Registration date

2025-09-05, 1404/06/14

Registrant information

Name

Milad Etemadi-Shalamzari

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-06, 1404/06/15

Expected recruitment end date

2025-09-11, 1404/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of palatal mucosa anesthesia due to infiltration of lidocaine compared to articaine in the buccal region of maxilla

Public title
Evaluation of palatal mucosa anesthesia due to infiltration of lidocaine compared to articaine
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All people who are candidates for implants on both sides of the maxilla
Exclusion criteria:
Age less than 18 years History of trauma or nasal surgery History of psychiatric disorder Congenital anomalies Peripheral neuropathy or presence of sensory deficits in the facial area prior to surgery Uncontrolled systemic conditions
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **34**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
anesthesia during maxillary dental procedures. The study will be conducted as a randomized, double-blind, crossover clinical trial at the School of Dentistry, Isfahan University of Medical Sciences, Iran. Participants will be candidates for bilateral maxillary implant placement, with both sides scheduled for surgery in a single session, as performing bilateral maxillary implant surgery in one session is a common practice. During the session, buccal injections of both anesthetic agents (articaine and lidocaine) will be administered with an appropriate washout period to ensure that the effect of the first anesthetic is eliminated. Injections will be performed in the buccal region of the maxillary canine and first molar on both sides, and participants will be blinded to the type of anesthetic used. Considering that systemic conditions and pain thresholds may vary between treatment sessions, both sides will be evaluated within the same session while observing the washout period. A computerized injection device will be used to standardize the injection rate. Randomization will be performed and managed using an online software. For operator blinding, anesthetic cartridges will be color-coded (e.g., blue and red) so that the operator is unaware of the type of anesthetic. Prior to each injection, and after drying the buccal mucosa of the maxillary canine and first molar, a lidocaine gel will be applied to the site for one minute using an applicator.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Hezar Jerib Street
City
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Postal code
81746-73461
Approval date
2025-07-26, 1404/05/04
Ethics committee reference number
IR.MUI.DHMT.REC.1404.080

Health conditions studied

1

Description of health condition studied
Comparative evaluation of the effectiveness of articaine and lidocaine for achieving palatal anesthesia.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The amount of change in pain threshold
Timepoint
Before and 5 minutes after injection
Method of measurement
Light Touch (Semmes Weinstein monofilament) test

2

Description
The amount of change in sensory threshold
Timepoint
Before and 5 minutes after injection
Method of measurement
Light Touch (Semmes Weinstein monofilament) test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants are randomly assigned to receive articaine anesthesia on one side of the maxilla (left or right) which half a cartridge (equivalent to 0.9 mL) was injected at the canine region and the same amount at the first maxillary molar region using the infiltration technique.
Category
Treatment - Drugs

2

Description
Control group: Participants randomly receive lidocaine on the contralateral side of the maxilla (e.g., the left side if articaine was administered on the right) which half a cartridge (equivalent to 0.9 mL) was injected at the canine region and the same amount at the first maxillary molar region using the infiltration technique.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry, Isfahan University of Medical Sciences
Full name of responsible person
Dr. Milad Etemadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Milad Etemadi
Position
Assistant Professor
Latest degree
Specialist
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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
Yes - There is a plan to make this available
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
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
All data is potentially shareable after de-identifying individuals.
When the data will become available and for how long
Access period starts 6 months after results are published
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
.No other condition
From where data/document is obtainable
Address: Faculty of Dentistry, Isfahan University of Medical Sciences, Tel: 03137925521
What processes are involved for a request to access data/document
.10 day after sending the request,data will be accessible
Comments