

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

Country

Iran (Islamic Republic of)

Phone

+98 31 1391 3237

Email address

etemadi@dnt.mui.ac.ir

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

Isfahan

Province

Isfahan

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

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 5552

Email

dnt@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Rouhollah Nasserri

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 5521

Email

dnt@mui.ac.ir

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

Other areas of specialty/work

Dentistry

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 5521

Email

etemadi@dnt.mui.ac.ir

Person responsible for scientific 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

Other areas of specialty/work

Dentistry

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 5521

Email

etemdi@dnt.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Milad Etemadi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 5521

Email

etemdi@dnt.mui.ac.ir

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