

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Articaine 4% and Lidocaine 2% for Buccal Infiltration After Inferior Alveolar Nerve Block For Intraoperative Pain Control During Impacted Mandibular Third Molar Surgery

Protocol summary

Study aim

Comparison of buccal articaine infiltration of 4% and lidocaine 2% after anesthesia of lower alveolar nerve block in pain control during mandibular occlusal surgery

Design

Parallel double-blind randomized clinical trial

Settings and conduct

4% articaine and 2% Lidocaine with 1: 200,000 epinephrine are both made by Elixir Factory. After the anesthetic was injected, the time of onset of anesthesia was recorded with a chronometer. The use of chi-square test was evaluated. A ten-digit VAS system was used to evaluate the pain during removal of the third molar of the mandible using an elevator or milling machine and pain after surgery up to 15 hours after surgery.

Participants/Inclusion and exclusion criteria

Third Molar Surgery Indication

Intervention groups

Articaine and Lidocaine Group

Main outcome variables

Pain - adverse effect

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220524054979N1**

Registration date: **2022-07-16, 1401/04/25**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-16, 1401/04/25**

Update count: **0**

Registration date

2022-07-16, 1401/04/25

Registrant information

Name

Samaneh Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 4433 3600

Email address

mmd.samaneh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Articaine 4% and Lidocaine 2% for Buccal Infiltration After Inferior Alveolar Nerve Block For Intraoperative Pain Control During Impacted Mandibular Third Molar Surgery

Public title

Painkiller effect of 4% Lidocaine versus 4% Articaine after wisdom teeth extraction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Mandibular Third Molar Surgery Indication

Exclusion criteria:

Systemic Disease Analgesics Consumption during last 24 hours Allergic Reaction to Local Anesthesia Agents Hyperalgesic Syndrome Pregnancy and Lactating

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize, patients are divided into two groups using the blocks made by statistical software: In the first group, the surgery is conducted using Lidocaine 2%, and in the second group, the surgery is performed using Articaine 4%. All surgeries will be performed by an oral and maxillofacial surgeon and in one room with an assistant. The type of anesthesia will be selected randomly in the first surgery and will not be told to the surgeon prior to the start of injection and finishing the surgical procedure.

Blinding (investigator's opinion)

Double blinded

Blinding description

Researchers examining the parameters of anesthesia success will not be aware of the type of intervention performed on the patient. Also, patients themselves will not be aware of the intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Urmia University of Medical science ethics in Biomedicine researches committee

Street address

Alborz

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2021-11-16, 1400/08/25

Ethics committee reference number

IR.UMSU.REC.1400.309

Health conditions studied

1

Description of health condition studied

Oral Surgery

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes

1

Description

Postoperative Pain

Timepoint

7, 4 and 21 days

Method of measurement

Visual Analog Scale

2

Description

Anesthesia Duration

Timepoint

0-12

Method of measurement

Cronometer

3

Description

Anesthesia Start

Timepoint

0-12

Method of measurement

Watch

4

Description

Surgery Duration

Timepoint

0-10

Method of measurement

Cronometer

Secondary outcomes

empty

Intervention groups

1

Description

Local Anesthesia administration in the mandible with Articaine 4% (SeptocaineFrance, Septodont) (with 1:100000 Epinephrine,3.6 ml, using 27 gauge needle with the speed of 1 mL/min. The needle bevel was at the bone side. Group 1 : Inferior Alveolar nerve Block Anesthesia For Third Molar

Category

Treatment - Drugs

2

Description

Local Anesthesia administration in the mandible with Lidocaine 2% (xylopen; Exir pharmaceutical Co, Iran) (with 1:100000 Epinephrine,3.6 ml, using 27 gauge needle with the speed of 1 mL/min. The needle bevel was at the bone side. Group 1 : Inferior Alveolar nerve Block Anesthesia For Third Molar

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Alborz Clinic

Full name of responsible person

Farhad Nojan

Street address

Alborz

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3336 3600

Email

farhad_nojan@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urmia Dental Clinic

Full name of responsible person

Dr. Samaneh Mohammadi

Street address

Alborz

City

Urmia

Province

West Azarbaijan

Postal code

:5714783734

Phone

+98 44 3336 3600

Email

mmd.samaneh@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Urmia Dental Clinic

Proportion provided by this source

80

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

Urmia University of Medical science

Full name of responsible person

Ehsan Hooshyar

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Alborz

City

Urmia

Province

West Azarbaijan

Postal code

:5714783734

Phone

+98 44 3336 3600

Email

Hooshyar.e@umsu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Urmia University of Medical Science

Full name of responsible person

Farhad Nojan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Alborz

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3336 3600

Email

farhad_nojan@yahoo.com

Phone

+98 44 4433 3600

Fax**Email**

mmd_samaneh@gmail.com

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

No

When the data will become available and for how long

After Publication

To whom data/document is available

Patients

Under which criteria data/document could be used

Informed Consent

From where data/document is obtainable

Clinicians

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

Online Access

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Samaneh Mohammadi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Alborz

City

Urmia

Province

West Azarbaijan

Postal code

:5714783734