

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of Anesthesia Efficiency of Local Infiltration with Articaine 4% and Mental Nerve Block with Lidocaine 2% in Extraction of Mandibular Anterior Teeth

Protocol summary

Study aim

Comparison of anesthesia efficiency of local infiltration with articaine 4% and mental nerve block with lidocaine 2% in extraction of mandibular anterior teeth

Design

A clinical trial with parallel, double-blind, randomized, phase 3 groups on 54 patients was used for Excel software randomization.

Settings and conduct

Patients referred to Alborz Dental Clinic in Urmia for extraction of mandibular anterior teeth and interested in participating in this study, will be divided into two groups: lidocaine recipient and articaine recipient. In both groups, the standard injection with a 25 gauge needle with a short length will be performed slowly (1 minute) by a surgeon under the same conditions. Epinephrine 1: 100000 vasoconstrictor (made by Iran Elixir) will be injected for buccal infiltration and 0.3ml (about one-eighth of the cartridge) for lingual infiltration. In the second group, after needle insertion and negative blood aspiration, 1.5 ml of 2% lidocaine anesthetic solution with vasoconstrictor epinephrine 1: 100000 (made by Iran Elixir) by mental block method and 0.3 ml (about one-eighth of the cartridge)) Will also be injected for lingual infiltration.

Participants/Inclusion and exclusion criteria

Patients with age range of 18-45 At least one mandibular anterior tooth No systemic problems No allergies to anesthetic solutions used Absence of inflammation and soft tissue infection near the injection site Do not take painkillers 24 hours before treatment

Intervention groups

In the first group, 4% articaine anesthetic solution with 1: 100000 epinephrine vasoconstrictor (made by Iran Elixir) and in the second group, 2% lidocaine anesthetic solution with 1: 100000 epinephrine vasoconstrictor (made by Iran Elixir) will be injected.

Main outcome variables

Pain level of patients during surgery based on SEM scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220117053751N1**

Registration date: **2022-03-30, 1401/01/10**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-30, 1401/01/10**

Update count: **0**

Registration date

2022-03-30, 1401/01/10

Registrant information

Name

amir soltanpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3336 3600

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of Anesthesia Efficiency of Local Infiltration with Articaine 4% and Mental Nerve Block with Lidocaine 2% in Extraction of Mandibular Anterior Teeth

Public title
Evaluation of Anesthesia Efficiency of Local Infiltration with Articaine 4% and Mental Nerve Block with Lidocaine 2% in Extraction of Mandibular Anterior Teeth

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with age range of 18-45 At least one mandibular anterior tooth No systemic problems No allergies to anesthetic solutions used Absence of inflammation and soft tissue infection near the injection site Do not take painkillers 24 hours before treatment
Exclusion criteria:
 systemic problems like diabet allergies to anesthetic solutions used inflammation and soft tissue infection near the injection site take painkillers 24 hours before treatment

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly divided into two groups of 27 based on limited randomization and using the law of random allocation. Randomization based on a single sequence of random allocations is called simple or unlimited randomization. Simple randomization is one of the most common methods used to perform the randomization process. In this method, there is a possibility of inequality in the number of people assigned to each group, especially in studies with a small sample size. While according to the probability hypothesis, with increasing the sample size, this inequality will be greatly reduced and the division will be based on the coin toss.

Blinding (investigator's opinion)
Double blinded

Blinding description
Researchers will be blind to the process of randomization and sample allocation. The patient's pain will be assessed by a second person who will be on the blind injection.

Placebo

Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of urmia University of Medical Sciences

Street address

Orjans ave,urmia University of Medical Sciences

City

urmia

Province

West Azarbaijan

Postal code

2344675432

Approval date

2021-11-09, 1400/08/18

Ethics committee reference number

IR.UMSU.REC.1400.349

Health conditions studied

1

Description of health condition studied

compare anesthesia drugs

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

during tooth extraction

Method of measurement

The SEM scale will be used to measure the patient's pain during treatment, which is a ranking variable. The SEM scale for measuring pain is a valid, useful and easy-to-use scale that is used in various researches. This scale includes recording of the patient's voice (Sound), examination of the eyes (Eyes) and patient movements (Motor), which will be recorded separately for each treatment, after the injection.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Anesthetic recipient Local infiltration with 4% articaine with lingual infiltration, standard injection with 25 gauge needle with short length will be done slowly (1 minute) by a surgeon in the same conditions. After the needle is inserted. And negative blood aspiration, 1.5 ml of 4% articaine anesthetic solution with 1: 100000 epinephrine vasoconstrictor (made by Iran Elixir) for buccal infiltration and 0.3 ml (about one-eighth of the cartridge) for lingual infiltration will be injected.

Category

Treatment - Surgery

2

Description

Intervention group 2: After needle insertion and negative blood aspiration, 1.5 ml of 2% lidocaine anesthetic solution with 1: 100000 epinephrine vasoconstrictor (made by Iran Elixir) by mental nerve block method and 0.3 ml (about one-eighth of the cartridge) Will also be injected for lingual infiltration.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alborz dental clinic

Full name of responsible person

Farhad Nojan

Street address

Alborz st,Alborz dental clinic

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urmia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Amir Soltanpour

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available