Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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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
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Sponsors / Funding sources

1

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Name of organization / entity
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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
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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