

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effectiveness between conventional and modified inferior alveolar nerve block techniques

Protocol summary

Study aim

The aim of this study is to compare the success rate between the conventional and modified inferior alveolar nerve block techniques.

Design

The groups were considered as conventional (control) and modified (intervention). Coin randomization is performed to start and determine the initial position in every patient, and each patient (Single-blinded) selects one of the numbers between 1 and 2 (in different envelopes) as the injection method 2 is modified and 1 is conventional. The sample size considered 42 persons. Trial is a therapeutic type.

Settings and conduct

Referrals to the oral and maxillofacial Surgery department, Dentistry school, Islamic Azad University, Tehran, which have indication of anesthesia in both posterior mandibular teeth by Split-mouth and single blind (patients) method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1 - Indication to block Inferior alveolar nerve for posterior mandibular tooth extractions bilaterally. 2 - Among 18 to 55 years-old Exclusion criteria: 1 - Systemic diseases 2 - Infection and swelling in the area 3 - The anesthetic solutions sensitivity 4 - History of surgery or ramus fracture 5 - Any analgesic 6 - Psychiatry disorders

Intervention groups

1 - conventional method The syringe body is placed on the opposite premolars and needle enters $\frac{3}{4}$ anterior posterior distance from Coronoid process to pterygomandibular raphe. 2 - modified technique The syringe body is placed on the occlusal of the first molar tooth on the opposite side and needle enters perpendicular to the medial mandibular ramus just lateral to the pterygomandibular fold. In both methods, needle enters on 10 mm or so above the occlusal plane and parallel to it.

Main outcome variables

1 - The success rate of injection method 2 - Time to start numbness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150924024167N2**

Registration date: **2020-03-07, 1398/12/17**

Registration timing: **retrospective**

Last update: **2020-03-07, 1398/12/17**

Update count: **0**

Registration date

2020-03-07, 1398/12/17

Registrant information

Name

Esshagh Lasemi

Name of organization / entity

Oral&Maxillofacial surgery Department-Dental Branch, Islamic Azad University, Tehran

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

2017-09-23, 1396/07/01

Actual recruitment end date

2019-09-23, 1398/07/01

Trial completion date

2019-10-07, 1398/07/15

Scientific title

Comparison of the effectiveness between conventional and modified inferior alveolar nerve block techniques

Public title

Comparing of effectiveness of two anesthetic techniques on inferior alveolar nerve block

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who need the bilateral IANB for posterior mandibular tooth extractions.

Exclusion criteria:

Systemic diseases Infection in the area History of sensitivity reaction to the anesthetic solutions History of surgery or fracture of the ramus Any medicament altering the pain perception Psychiatry disorders

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **37**

More than 1 sample in each individual

Number of samples in each individual: **2**

One side of the mandible once, and then on the opposite side

Actual sample size reached: **42**

More than 1 sample in each individual

Actual sample size in each individual: **2**

One side of the mandible once, and then on the opposite side

Randomization (investigator's opinion)

Randomized

Randomization description

The study is performed using the split-mouth method (each side of the mandible as a group) and with the coin method, the starting position (left or right) will be selected for every patient; then each patient, without knowing which numbers correspond to any of the methods, chooses between 1 and 2 numbers in different envelopes (2 as modified and 1 as conventional) to get started.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are unaware of the type of anesthesia and side of mandible, which will be performed first.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Islamic Azad University of Medical Sciences, Dental school

Street address

No.9, Neyestan 9th, Pasdaran Ave.

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2017-02-27, 1395/12/09

Ethics committee reference number

IR.IAU.DENTAL.REC.1395, 25

Health conditions studied**1****Description of health condition studied**

Indication of posterior teeth anesthesia in the form of bilateral

ICD-10 code

DA07.8

ICD-10 code description

DA07.8: An impacted tooth is a tooth that is all the way or partially below the gum line and is not able to erupt properly. Wisdom teeth (third molars) as the most commonly impacted teeth; DA0A.1: extraction or local periodontal disease.

Primary outcomes**1****Description**

Comparison of success rates between conventional and modified technique in the inferior alveolar nerve block

Timepoint

During the intervention

Method of measurement

Inquiring from patient - Observing, Testing and Measuring by the Researcher

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: as modified technique, a 1.8 cc Lidocaine 2% anesthetic solution with 1.80000 epinephrine is used. The syringe body is placed on the occlusal of the first molar on the opposite side, and needle enters perpendicular to the medial mandibular ramus just lateral to the pterygomandibular fold and needle enters on 10 mm or so above the occlusal plane and parallel to it. The techniques will be considered successful if the lip and tongue is anesthetized after 5 minutes and if did not happen for another 5 minutes the injection will be repeated one time more.

Category

Treatment - Other

2

Description

Control group: as conventional method, a 1.8 cc Lidocaine 2% anesthetic solution with 1.80000 epinephrine is used. The syringe body is placed on the opposite premolars and needle enters ¾ anterior posterior distance from Coronoid process to pterygomandibular raphe and with the line that is perpendicular to it from the tuberosity, and needle enters on 10 mm or so above the occlusal plane and parallel to it. The techniques will be considered successful if the lip and tongue is anesthetized after 5 minutes and if did not happen for another 5 minutes the injection will be repeated one time more.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral and maxillofacial surgery department, school of dentistry, Islamic Azad university of medical s

Full name of responsible person

Esshagh Lasemi

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Web page address

<http://dental.iautmu.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad university of medical science, school of dentistry

Full name of responsible person

Arash Azizi

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drarashazizi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad university of medical science, school of dentistry

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

Islamic Azad University

Full name of responsible person

Esshagh Lasemi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Oral and maxillofacial surgery

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Position

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Latest degree

Specialist

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Person responsible for updating data

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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

Not applicable

Data Dictionary

Not applicable