# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 ¾ 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**

Iran (Islamic Republic of)

**Phone**

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**Email address**

e_lasemi@dentaliau.ac.ir

**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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elasemi@yahoo.com

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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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No.9, Neyestan 9th, Pasdaran Ave.

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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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## Person responsible for scientific inquiries

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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