

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Neurosensory disturbance following the inferior alveolar nerve block in the extraction of the third molars.

Protocol summary

Study aim

Evaluation of the probability of neurosensory disturbance of inferior alveolar nerve (IAN) after IAN block with articaine compared with lidocaine

Design

The clinical trial is performed as randomized, blinded, and two arm parallel design of 1000 patients. The randomization was done by picking patients' names from matted pockets.

Settings and conduct

The study was performed on candidates for extraction of mandibular third molar in dentistry faculty of Shahid Beheshti university and its dependent dental clinics (Behfar and Ghazitabatabai clinics). Following taking an informed consent for extraction and the study, patients were seated on a dental unit, injection of the inferior alveolar nerve block was performed and after 15 minutes, the tooth was extracted. Patients were discharged after taking proper hygiene instructions.

Participants/Inclusion and exclusion criteria

Inclusion criteria consist of patients who need extraction of their erupted mandibular wisdom tooth that the apex has sufficient distance from inferior alveolar nerve canal and are systemically healthy and the patient age is between 15 to 60 years old. Exclusion criteria is a history of surgery or trauma to the mandible

Intervention groups

The intervention group receives articaine for inferior alveolar nerve block. The control group receives lidocaine for inferior alveolar nerve block

Main outcome variables

Incidence of neurosensory disturbance in inferior alveolar nerve

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221203056693N1**

Registration date: **2023-03-02, 1401/12/11**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-02, 1401/12/11**

Update count: **0**

Registration date

2023-03-02, 1401/12/11

Registrant information

Name

Amir Mazidi Sharafabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2277 7437

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Panahiniamahsa@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Neurosensory disturbance following the inferior alveolar nerve block in the extraction of the third molars.

Public title

Comparison of Neurosensory disturbance following the inferior alveolar nerve block

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients who are in normal healthy status Patients who need to remove mandibular third molars Patients with a sufficient distance between the third molars root and the inferior alveolar nerve
Exclusion criteria:
 Patients with disturbed inferior alveolar nerve Patients with a history of fracture or trauma to mandible Patients with history of surgery Patients with a history of surgery of a mandibular pathologic lesion Patients who have done cosmetic surgery or augmentation at mandible Patients taking psychologic medications

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **1000**

Randomization (investigator's opinion)
Randomized

Randomization description
The names of the patients were put in a pocket in separate papers and were taken out blindly and were divided into two groups alternatively.

Blinding (investigator's opinion)
Double blinded

Blinding description
The labels of the anesthetic cartridges were removed and marked by numbers 1 and 2. the cartridges were applicated neither the dentist nor the patient knowing the type of anesthetic solution. The patients were consented to participate in the study but not aware of the type of anesthetics. Evaluation of the neurosensory disturbances was done by an epidemiologist and the researcher to define statistical and clinical significance of difference, while both were unaware of the type of the anesthetic solution. In this study, patients, dentists, the data analyst, and the researcher were blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Tehran Province, Tehran, Velenjak, 7th Floor, Bldg No.2 SBUMS, Arabi Ave

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2020-08-22, 1399/06/01

Ethics committee reference number

IR.SBMU.DRC.REC.1399.061

Health conditions studied

1

Description of health condition studied

Neurosensory disturbance of inferior alveolar nerve

ICD-10 code

G50.9

ICD-10 code description

disorder of trigeminal nerve, unspecified

Primary outcomes

1

Description

Incidence of neurosensory disturbance

Timepoint

Evaluation of the neurosensory disturbance 24 hours, 1 week, 2 weeks, one and 4 months after the extraction

Method of measurement

Neurosensory evaluation was performed by brush test. Patients' eyes were covered and the chin area were brushed and the patients were asked about the direction of the brushing. the results were recorded as true or false.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Lidocaine 0.2% with epinephrine 1:80000 (Perzocaine - E, Darupakhsh, Tehran, Iran). For each patient, two 1.8 cc carpule were injected for inferior alveolar nerve block, each one in 45 seconds period. patients were undergone the procedure only once during the study.

Category

Prevention

2

Description

Intervention group: Articaine 4% with epinephrine 1:200000 (Dentacaine, Exir, Tehran, Iran). For each patient, two 1.8 cc carpule were injected for inferior alveolar nerve block, each one in 45 seconds period. patients were undergone the procedure only once during the study.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti dental school

Full name of responsible person

Reza Tabrizi

Street address

Daneshjou Blvd, District 1, Tehran, Tehran Province,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hadi ghasemi

Street address

Daneshjou Blvd, District 1, Tehran, Tehran Province,

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amir Mazidi Sharafabadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza Tbrizi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Position
Resident
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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

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts one month after the results are published

To whom data/document is available

The data will be accessible to all

Under which criteria data/document could be used

There is no special condition in this regard

From where data/document is obtainable

To receive the data, a request should be sent to the e-mail address of Dr. Mazidi at the address below:
amir.mazidi@ymail.com

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

After sending the application to the mentioned E-mail address, the applicant will receive the information within 7 to 30 days

Comments