Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Inferior Alveolar Nerve Block Versus Local Infiltration with 2% Lidocaine for Pain Management in Posterior Mandible Implant Surgery: A Randomized Double-Blind Controlled Trial

Protocol summary

Study aim

This study aims to compare the analgesic effects of the Inferior Alveolar Nerve Block (IANB) and local infiltration anesthesia using 2% lidocaine in mandibular posterior implant surgery.

Design

This study was a randomized, double-blind, parallel-group clinical trial with a split-mouth design. A total of 31 patients are going to be enrolled and undergo bilateral mandibular implant surgeries during a single session. Randomization was performed using block randomization (blocks of 4) generated by Excel software.

Settings and conduct

The study will be conducted at the implant sector of the School of Dentistry, Tehran University of Medical Sciences. Patients and the evaluators will be blinded to the type of anesthesia administered. However, the statistician and the surgeon will not be blinded due to their roles in randomization and surgical procedures.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Systemically healthy adults (≥18 years). Candidates for bilateral implant placement in first/second molars. Fully healed/adequately reconstructed alveolar ridge at surgical site. Exclusion Criteria: Systemic contraindications to surgery. Untreated periodontal disease. Medications affecting pain perception within 48 hours of surgery. Pathological conditions at the injection site. Immediate implant placement or requiring bone grafting. Dental anxiety/phobia, neurological disorders, familiarity with injection techniques (e.g., dental professionals).

Intervention groups

Group 1: half of the mouth is anesthetized by Inferior Alveolar Nerve Block (IANB) using 2% lidocaine with 1:100,000 epinephrine Group 2: The other half of the mouth is anesthetized by local infiltration using 2% lidocaine with 1:100,000 epinephrine

Main outcome variables

The primary outcome variable will be the pain intensity during surgery and 24 hours post-surgery, measured using the Visual Analogue Scale (VAS).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250429065518N1**
Registration date: **2025-05-22, 1404/03/01**
Registration timing: **retrospective**

Last update: **2025-05-22, 1404/03/01**
Update count: **0**

Registration date

2025-05-22, 1404/03/01

Registrant information

Name

Nima Dehghani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 912 618 0690

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nimadt2002@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-21, 1403/10/01

Expected recruitment end date

2025-03-15, 1403/12/25

Actual recruitment start date

2024-12-21, 1403/10/01

Actual recruitment end date

2025-04-14, 1404/01/25

Trial completion date

2025-05-21, 1404/02/31

Scientific title

Effectiveness of Inferior Alveolar Nerve Block Versus Local Infiltration with 2% Lidocaine for Pain Management in Posterior Mandible Implant Surgery: A Randomized Double-Blind Controlled Trial

Public title

Comparison of Analgesic Effect of Inferior Alveolar Nerve Block and Lidocaine Infiltration in Posterior Mandibular Implant Placement: A Split-Mouth Randomized Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Eligible patients were aged 18 or older. Systemically healthy Candidates for bilateral implant surgery in the first or second molar region It was essential that the alveolar ridge in the surgical site had fully healed and reconstructed adequately.

Exclusion criteria:

Patients with systemic conditions contraindicating surgery or an allergy to local anesthetics. Pregnant individuals Heavy smokers Individuals suffering from untreated periodontal conditions. Patients who had taken medications affecting pain perception (such as analgesics, antidepressants, or sedatives) within 48 hours prior to surgery. Individuals with active pathological conditions at the injection site. Cases requiring immediate implant placement. Cases needing bone grafting. Individuals suffering from extreme dental anxiety or phobia, or neurological disorders. Individuals who were familiar with the distinct injection techniques (e.g., dental professionals).

Age

From **28 years** old to **69 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

More than 1 sample in each individual

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

Each participant undergoes a randomized, blinded procedure in which one side is anesthetized using a nerve block and the other side using local infiltration for implant placement, all within the same patient during a single procedure.

Actual sample size reached: **31**

Randomization (investigator's opinion)

Randomized

Randomization description

randomization conducted using block randomization (blocks of 4), generated by Excel software.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this process, the patients and the evaluator responsible for assessing the pain are blinded to the contents of the envelopes. The statistician responsible for the randomization process and the surgeon performing the procedure could not be blinded. However, the patient and the evaluator responsible for assessing the patient’s pain are blinded and do not know which injection is performed on each side.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee at Tehran University of Medical Science

Street address

Secretariat of the Ethics Committee in Biomedical Research, Tehran University - Keshavarz Boulevard - Qods Street Intersection - Central Building of Tehran University of Medical Sciences - 6th Floor - Room 604

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-07-25, 1400/05/03

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1400.102

Health conditions studied

1

Description of health condition studied

implant placement in the posterior region of Mandible

ICD-10 code

Z96.5

ICD-10 code description

Presence of tooth-root and mandibular implants

Primary outcomes

1

Description
The primary outcome variable is pain intensity during surgery and 24 hours after surgery. Pain intensity was assessed using the Visual Analogue Scale (VAS).
Timepoint
Pain intensity will be measured during the surgery and at 24 hours post-surgery.
Method of measurement
Pain intensity will be measured using the Visual Analogue Scale (VAS).

Secondary outcomes

empty

Intervention groups

1

Description
The randomly selected hemi-mandible is going to be anesthetized using the IANB technique.
Category
Treatment - Surgery

2

Description
Control group: The randomly selected hemi-mandible is going to be anesthetized using the infiltration technique.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran University of Medical Sciences faculty of Dentistry, Implant sector
Full name of responsible person
Nima Dehghani
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Office of the Research Deputy, School of Dentistry, Tehran University of medical Sciences
Full name of responsible person
Sedigheh Hashemi Kamangar
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End of North Kargar Street, next to the Atomic Energy Organization, before the exit to Hakim East Highway, Tehran University of Medical Sciences, School of Dentistry
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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
Office of the Research Deputy, School of Dentistry, Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Nima Dehghani
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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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)

Yes - There is 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

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

Yes - There is a plan to make this available

Title and more details about the data/document

Comparison of Analgesic Effect of Inferior Alveolar Nerve Block and Lidocaine Infiltration in Posterior Mandibular Implant Placement: A Split-Mouth Randomized Clinical Trial The following data/documents will be shared: De-identified Individual Participant Data (IPD): Includes demographic information, procedural data, pain scores (VAS), and outcomes related to anesthesia techniques. Study Protocol Document: Encompasses the experimental design, ethical approvals, and statistical analysis methods. Thesis and Article Files: Includes the complete thesis and the final published article documenting the study. Consent Forms: Translated versions of patient information sheets and consent forms, upon qualified request.

When the data will become available and for how long

The data/documents will be available 6 months after the publication of the main study results. The availability period will last for an indefinite period

To whom data/document is available

Researchers who are affiliated with recognized academic institutions. Healthcare policymakers and practitioners working in the field. Industry researchers, upon providing justified scientific use cases.

Under which criteria data/document could be used

To access the shared data/documents, applicants must: Submit a research proposal outlining intended analyses (e.g., secondary analyses, meta-analyses, validation studies). Agree to use the data ethically and responsibly, adhering to participant confidentiality standards. Allow publications to include only aggregate-level data, ensuring non-identifiable results. All requests will be reviewed by the research team and ethics committee, granting access based on scientific merit.

From where data/document is obtainable

Applicants can request data/documents by contacting: Contact Person: Dr. Nima Dehghani – Corresponding Author Email: nimadt2002@gmail.com Postal Address: Department of Oral and Maxillofacial Surgery, Tehran University of Medical Sciences, School of Dentistry, Postal Code: 1439955991 Phone: +9821-22273471 Fax: +9821-88497390

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

Submit a formal request including: Research Proposal Intended Data Use Administrative and ethical review

conducted by: Research team and ethics committee Sign a Data Use Agreement confirming compliance with ethical guidelines. The review process typically takes 2–4 weeks after receiving all required documents.

Comments

All shared data will be fully anonymized to protect participant confidentiality. Certain datasets may be restricted due to consent limitations or local regulations.