

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

A comparison of two anesthetic methods with 2% lidocaine for the surgical removal of impacted mandibular third molars: IAN block technique vs local infiltration technique

Protocol summary

Study aim

A comparison of two anesthetic methods with 2% lidocaine for the surgical removal of impacted mandibular third molars: IAN block technique vs local infiltration technique

Design

Cross-over and single-blind, randomized clinical trial on 30 patients. The rand function of Excel software will be used for randomization.

Settings and conduct

This study will be conducted in the Shahid Montazeri Clinic in Tehran city. Referral patients will be selected for wisdom tooth extraction who have wisdom teeth in the lower jaw on both sides. After providing the explanation and obtaining consent, the patients will randomly receive an infiltrate or block anesthesia injection for the first surgery. Injection type won't be shared with the patient and the evaluating researcher until the surgery is completed. In the second surgery, which will be performed at least three weeks later, anesthesia will be injected using the second method. The patient will be asked to discuss any discomfort with the surgeon. If the patient expresses pain, the surgery will be stopped and the anesthesia will be injected again according to the patient's condition, and the initial injection will be considered failed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with impacted lower jaw wisdom teeth
Exclusion criteria: patients with systemic disorders; patients using narcotic drugs; patients using sedatives; patients with active infection in the wisdom tooth area.

Intervention groups

In order to extract the wisdom teeth of the mandible in the patients included in the research, anesthesia injection will perform on one side by infiltration method and on the other side anesthesia injection will perform by

block method.

Main outcome variables

Pain during injection; Pain during surgery; Delay of anesthesia onset in surgical field; Delay of anesthesia onset in mental area; Delay of anesthesia onset in lower lip

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221015056184N1**

Registration date: **2022-11-27, 1401/09/06**

Registration timing: **prospective**

Last update: **2022-11-27, 1401/09/06**

Update count: **0**

Registration date

2022-11-27, 1401/09/06

Registrant information

Name

Mehdi Saberi Shakib

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6641 4151

Email address

mehdisaberishakib@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-06, 1401/09/15

Expected recruitment end date

2023-03-06, 1401/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparison of two anesthetic methods with 2% lidocaine for the surgical removal of impacted mandibular third molars: IAN block technique vs local infiltration technique

Public title
A comparison of two anesthetic methods: IAN block technique vs local infiltration technique

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 patients with symmetrical fully impacted lower third molars
Exclusion criteria:
 patients with systemic disorders drug consuming patients patients taking antianxiety drugs patients with active infection in the wisdom tooth area

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
 Target sample size: **30**
 More than 1 sample in each individual
 Number of samples in each individual: **2**
 lower impact third molar

Randomization (investigator's opinion)
Randomized

Randomization description
 In this study, randomization will be done according to the random allocation rule. In this way, before the start of the study, people will be divided into two equal groups. The procedure will be that the numbers one to thirty written on paper are poured into a container and fifteen papers are removed. These fifteen selected numbers will form the members of the first group and the rest of the numbers will form the members of the second group. The first group will receive an infiltration injection in the first session and the second group will receive a block injection in the first session.

Blinding (investigator's opinion)
Double blinded

Blinding description
 The volume of anesthetic injected on both sides is the same for each person. The anesthesia injection method is not discussed with the patient and the evaluating

researcher until the end of the surgery.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of shahed university

Street address

Floor 13, Block A The central headquarters of the Ministry of Health, Medical Treatment and Education, Simaye Iran Ave., Qods Town

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2022-02-21, 1400/12/02

Ethics committee reference number

IR.SHAHED.REC.1400.179

Health conditions studied

1

Description of health condition studied

Anesthesia effect of lidocaine solution in two methods: block and infiltration, in the posterior mandible

ICD-10 code

K01.1

ICD-10 code description

Impacted teeth

Primary outcomes

1

Description

Pain during anesthesia injection with infiltration method

Timepoint

Immediately after injection

Method of measurement

Visual Analogue Scale

2

Description

Pain during injection of anesthesia with block method

Timepoint

Immediately after injection

Method of measurement

Visual Analogue Scale

3

Description

Pain during surgery in infiltration anesthesia group

Timepoint

Immediately after surgery

Method of measurement

Visual Analogue Scale

4

Description

Pain during surgery in block anesthesia group

Timepoint

Immediately after surgery

Method of measurement

Visual Analogue Scale

5

Description

The delay in the onset of anesthesia in the surgical area, mental area, and lower lip in the infiltration anesthesia method.

Timepoint

One-minute intervals after anesthesia injection until the patient feels no pain

Method of measurement

Record the tissue numbing time after the injection

6

Description

The delay in the onset of anesthesia in the surgical area, mental area, and lower lip in the block anesthesia method.

Timepoint

One-minute intervals after anesthesia injection until the patient feels no pain

Method of measurement

Record the tissue numbing time after the injection

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In all the studied subjects, for the extraction of the wisdom teeth on one side of the lower jaw, anesthesia injection will perform by infiltration method. The solution to be used will be two carpules Lidocaine 2% with epinephrine 1 in 80000 manufactured by Loqman Company.

Category

Treatment - Surgery

2

Description

Control group: In all the studied subjects, for the extraction of the wisdom teeth that are hidden on one side of the lower jaw, anesthesia injection will perform by direct block (Halsted) method. The solution to be used will be two carpules Lidocaine 2% with epinephrine 1 in 80000 manufactured by Loqman Company.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Montazeri Dental Clinic

Full name of responsible person

Mahmoud Nasr Esfehiani

Street address

No. 71, West Jafari Shari Ave., South Shahid Azodi Ave., Karim-Khan Ave.

City

Tehran

Province

Tehran

Postal code

1598759811

Phone

+98 21 8890 9388

Email

publicrelation@shahed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Nooshin Jalayer Naderi

Street address

No. 39, Italia St., Vesal Shirazi St., District 6

City

Tehran

Province

Tehran

Postal code

1417755351

Phone

+98 21 8895 9210

Email

jalayer@shahed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed University
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
Shahed University
Full name of responsible person
Mehdi Saberi Shakib
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
No. 57, Vesal Shirazi Ave., Enghelab Eslami Ave.
City
Tehran
Province
Tehran
Postal code
1416863131
Phone
+98 21 6649 5118
Email
mehdisaberishakib@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahed University
Full name of responsible person
Mehdi Saberi Shakib
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
No. 57, Vesal Shirazi Ave., Enghelab Eslami Ave.
City
Tehran
Province
Tehran
Postal code
1416863131
Phone

+98 21 6649 5118
Email
mehdisaberishakib@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahed University
Full name of responsible person
Mehdi Saberi Shakib
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
No. 57, Vesal Shirazi Ave., Enghelab Eslami Ave.
City
Tehran
Province
Tehran
Postal code
1416863131
Phone
+98 21 6649 5118
Email
mehdisaberishakib@gmail.com

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
Yes - There is a plan to make this available
Analytic Code
Yes - There is 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
sex, age, anesthesia method, pain during injection, latency of anesthesia onset on surgical field, mental and lower lip, pain during surgery
When the data will become available and for how long
Access available 6 months after publication
To whom data/document is available
dental students and dentists
Under which criteria data/document could be used
The use of data is only allowed to know the research process and the accuracy of the content, and it is not allowed to use them for use in another study.
From where data/document is obtainable
Applicants should contact the following email address to receive data: mehdisaberishakib@gmail.com

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

It will be possible to receive the data after the request

through e-mail and authentication by providing the student number or pratitioner number

Comments