

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparision of the effectiveness of two local anesthetic techniques of Inferior alveolar nerve block (IANB) and intra periodontal ligament injection on the pain during the extraction mandibular posterior teeth

Protocol summary

Study aim

Comparison of the effectiveness of two local anesthetic techniques of Inferior alveolar nerve block (IANB) and intra periodontal ligament injection of the pain during extraction of mandibular posterior teeth

Design

Study is randomized clinical trial which is split mouth . we have 30 patients . In the split mouth method two symmetrical side of mouth is chosen for two different interventions hence the local factors are reduced and the sturdy will be more accurate. The study was two side blind which evaluator and patients weren't aware of the treatment groups. There were two groups of case and control.

Settings and conduct

the study is done in tehran azad dentistry school and other clinics . the patients and evaluators are blind .

Participants/Inclusion and exclusion criteria

all the patients indicated for bilateral mandibular posterior teeth extraction

Intervention groups

on the one side of the mandible Inferior alveolar nerve block is given and the other side intra peiodontal ligament injection is given

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190512043566N1**

Registration date: **2019-05-29, 1398/03/08**

Registration timing: **retrospective**

Last update: **2019-05-29, 1398/03/08**

Update count: **0**

Registration date

2019-05-29, 1398/03/08

Registrant information

Name

Shahrooz Shafae Fard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8861 3696

Email address

a.joudaki@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-30, 1398/02/10

Expected recruitment end date

2019-05-10, 1398/02/20

Actual recruitment start date

2019-04-30, 1398/02/10

Actual recruitment end date

2019-05-10, 1398/02/20

Trial completion date

2019-05-10, 1398/02/20

Scientific title

Comparision of the effectiveness of two local anesthetic techniques of Inferior alveolar nerve block (IANB) and intra periodontal ligament injection on the pain during the extraction mandibular posterior teeth

Public title

Comparision of two local anesthetic techniques of block and intra ligament on the pain during the extraction of teeth

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

patients indicated for bilateral mandibular posterior extraction

Exclusion criteria:

systemic disease Allergy Periapical lesions Sinus opening
Fistula Periodontal pocket Severe infection Abscess

Age

From **25 years** old to **60 years** old

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**

The study is Split Mouth . Two anesthetic techniques each one on one side of the mandible is used .

Actual sample size reached: **30**

More than 1 sample in each individual

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

The study is Split Mouth . Two anesthetic techniques each one on one side of the mandible is used .

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization will be used. The randomization is done using randomized table and patients are allocated to two groups. After doing the task the evaluator is asked to evaluate the pain and the numbers are sent to analyzer.

Blinding (investigator's opinion)

Double blinded

Blinding description

patients and evaluator are not aware of which anesthetic technique used for which side .

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of university of Azad eslami , school of dentistry tehran iran

Street address

No. 4 , 9th neyestan , pasdaran

City

Tehran

Province

Tehran

Postal code

19585/175

Approval date

2019-04-28, 1398/02/08

Ethics committee reference number

IR.IAU.DENTAL.REC.1398.002

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

comparison of effectiveness of two anesthetic techniques of IANB and intra periodontal ligament injection

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

pain during tooth extraction

Timepoint

during tooth extraction

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: anesthetic injection by intra periodontal ligament injection technique. The intra ligament injection technique is a new technique which uses a new syringe called Arain made in Pakistan. The needle's tip is inserted inside the gingival sulcus of the tooth and injected. It's done in around the tooth for four times to achieve the anesthesia. The anesthetic solution used is 2% lidocaine + 1:800000 adrenalin. 0.24 ml of anesthetic is used for each tooth

Category

Other

2**Description**

Control group: anesthetic injection by inferior alveolar nerve block technique. The normal syringe with needle of gauge 25 is used. 1.8 ml of anesthetic is injected.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

azad university tehran dentistry school

Full name of responsible person

Ali Joudaki

Street address

No. 4 , 9th neyestan , pasdaran

City

Tehran

Province

Tehran

Postal code

19585/175

Phone

+98 21 2256 4571

Email

a.joudaki@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahrooz Shafae Fard

Street address

No. 4 , 9th neyestan , pasdaran

City

tehran

Province

Tehran

Postal code

19585/175

Phone

+98 21 2256 4571

Email

a.joudaki@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. shahrooz Shafae Fard

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

No . 4, 9th neyestan , pasdaran

City

Tehran

Province

Tehran

Postal code

19585/175

Phone

+98 21 2256 4571

Email

chavosh_joudaki@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. shahrooz Shafae Fard

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

No . 4, 9th neyestan , pasdaran

City

Tehran

Province

Tehran

Postal code

19585/175

Phone

+98 21 2256 4571

Email

chavosh_joudaki@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. shahrooz Shafae Fard

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

No . 4, 9th neyestan , pasdaran

City

Tehran

Province

Tehran

Postal code

19585/175

Phone

+98 21 2256 4571

Email

chavosh_joudaki@yahoo.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

some parts of data

When the data will become available and for how long

2021

To whom data/document is available

everyone

Under which criteria data/document could be used

any condition

From where data/document is obtainable

00989129253390

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

email

Comments