

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 + 1:80000 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

Other

## 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

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19585/175

**Phone**

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**Email**

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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**

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**

Academic

## 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**

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**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**

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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**

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**