Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Shafaee 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 techniqus 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 techniqus 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 Shafaee 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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. shahrooz Shafaee 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 Shafaee 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 Shafaee 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