Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the efficacy of Inferior alveolar nerve block (IANB), IANB along with buccal infiltration and modified intraseptal of Articaine in mandibular molars affected with irreversible pulpitis

Protocol summary

Summary

The purpose of this prospective, randomized, double-blind clinical study is to compare the efficacy of inferior alveolar nerve block (IANB), IANB with buccal infiltration and modified antraseptal injection of articaine in mandibular molars with irreversible pulpitis. Ninety healthy patients with the diagnosis of symptomatic irreversible pulpitis and normal periapical in mandibular molars will participate in this study and allocate randomly in three groups. The patients are asked to rate their pain on VAS after using cold test (VAS1). The teeth also are tested using electrical pulp tester (EPT1). In first group patient will receive standard IANB injection using 1.8 ml of 2% lidocaine with 1:100,000 epinephrine. In the second group they will be administrated standard IANB using 1.8 ml of 2% lidocaine with 1:100,000 epinephrine and buccal infiltration using 1.8 ml of 4% articaine with 1:100,000 epinephrine. In the third group, the patient will receive modified intraseptal using 1.8 ml of 4% articaine with 1:100,000 epinephrine. The injection of 1 ml anesthetic solution in the buccal vestibule and 0.8 ml of anesthetic solution in the mesial and distal dental papilla is considered as modified intraseptal . All injections will be done by a single operator. After 10 minutes, the pulpal anesthesia will be measured by electrical pulp tester (EPT2), then the access cavity will be prepared. If patients do not report lip numbness 10 minutes after IANB injection, they exclude from the study. Patients will be instructed to rate any discomfort during access on the Heft-Parker visual analogue (VAS2) scale. The success of anesthesia are defined as reading EPT ≥80 and the ability to access the tooth with no or mild pain (VAS ≤54).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015073023412N1**
Registration date: **2017-10-15, 1396/07/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-10-15, 1396/07/23

Registrant information

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Dental School of Shahid Beheshti University of Medical science
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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-07-31, 1395/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the efficacy of Inferior alveolar nerve block (IANB), IANB along with buccal infiltration and modified intraseptal of Articaine in mandibular molars affected with irreversible pulpitis

Public title
The efficacy of three different anesthetic technique in mandibular molars

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Healthy patients; aged 18 to 65 years; No allergy to lidocaine or articaine with 1:100,000 epinephrine; No pregnancy; having mandibular molars teeth with irreversible pulpitis and normal periapical radiographic appearance; Clinical diagnosis of irreversible pulpitis was confirmed by a positive response to an electric pulp test and a prolonged response with moderate to severe pain to a cold test using Roeko Endo-Frost . Exclusion criteria: presence of periodontal ligament (PDL) widening or periapical radiolucency; recently taken nervous system depressant or analgesic medication within 12 hours before treatment; absence of vital coronal pulp tissue during access preparation; failure to report lip numbness 10 minutes after Inferior alveolar nerve block injection.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Random number table will use for randomization patients and clinician who record the results do not aware of type of intervention

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Shahid Behsheti University of Medical Science

Street address
Daneshju Blv. Evin Blv. Chamran highway

City
Tehran

Postal code
1983963113

Approval date
2015-12-22, 1394/10/01

Ethics committee reference number
ir.sbmu.rids.rec.1394.77

Health conditions studied

1

Description of health condition studied
pulpitis

ICD-10 code
K04

ICD-10 code description
Diseases of pulp and periapical tissues, irreversible pulpitis

Primary outcomes

1

Description
pain

Timepoint
Befor intervention and 10 minutes after intervention

Method of measurement
Heft- parker Visual analog scales

Secondary outcomes

1

Description
Pulp sensivity

Timepoint
Before injection and 10 minutes after injection

Method of measurement
Electerical pulp test

Intervention groups

1

Description
group I: inferior alveolar nerve block (IANB) injection of 1.8 ml of 2% lidocaine with epinephrin 1;100000

Category
Treatment - Drugs

2

Description
group II: inferior alveolar nerve block injection of 1.8 ml

lidocaein 2% with epinephrin 1:100000 and buccal infiltration of 1.8 ml articaine 4% with epinephrin 1:100000

Category

Treatment - Drugs

3

Description

group III: intraseptal injection of 0.8 ml articaine 4% with epinephrine 1:100000 and bucal infiltration of 1ml articaine 4% with epinephrine 1:100000

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Omid Dianat

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City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Rezghi

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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

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty