

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of Success Rate of Inferior Alveolar Nerve Block versus IntraOsseous Injection For Pulpal Anesthesia in The Posterior Mandibular Teeth with Irreversible Pulpitis in patients attending to Afzal dental clinic, Isfahan, Iran 1391-92

Protocol summary

Summary

Aim: To compare the success rate of inferior alveolar nerve block (IANB) versus intraosseous (IO) injection for pulpal anesthesia in the posterior mandibular teeth with irreversible pulpitis in patients attending to Afzal dental clinic in order to replace the IO as a primary anesthesia in pulp therapy Design: An interventional randomized single-blinded study, unicentric, with control group and without placebo Method: 50 patients aged 18 to 65 years old with at least one posterior mandibular tooth with irreversible pulpitis for pulp therapy enrolled voluntarily to the study since 2012 to 2013. They should not have any history of taking any medication that would alter the inflammatory response of the pulp or provide analgesia for the previous 14 days. Any history of allergy to anesthetic solutions causes to exclusion of the patient. Patients divided to two groups randomly. For the case group, primary pulpal anesthesia will provide with Intra Osseous injection of Mepivacaine 3%. For the control group, primary pulpal anesthesia will provide with Inferior Alveolar Nerve Block injection of Mepivacaine 3%. Effect onset of anesthesia, persistence of anesthesia, degree of pain during pulp therapy and blood pressure changes after anesthesia injection will be evaluated and the results will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013022712634N1**

Registration date: **2013-12-25, 1392/10/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-12-25, 1392/10/04

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2012-10-05, 1391/07/14

Expected recruitment end date

2013-10-06, 1392/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Success Rate of Inferior Alveolar Nerve Block versus IntraOsseous Injection For Pulpal Anesthesia in The Posterior Mandibular Teeth with Irreversible Pulpitis in patients attending to Afzal dental clinic,

Isfahan, Iran 1391-92

Public title

Comparison of Anesthesia Success Rate in Mandibular Inflammatory Tooth Between two Different Injection Techniques

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Patients with at least one posterior mandibular tooth with irreversible pulpitis for pulp therapy that each pulp therapy would be applicable thoroughly in one visit; 2) No history of taking any medication that would alter the inflammatory response of the pulp or provide analgesia for the previous 14 days; 3) No history of major systemic or cardiovascular disease; 4) Patients aged 18 to 65 years old; 5) Absence of acute inflammation and advanced periodontal disease at the injection area; 6) Provision written informed consent; Exclusion criteria: 1) Any history of allergy to anesthetic solutions; 2) lack of cooperation or interest of patient to continue the study.

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: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Bioethics Committee of Isfahan University of Medical Sciences

Street address

Building number 4, Isfahan University of Medical Sciences, Hezar Jarib Ave

City

Isfahan

Postal code

Approval date

2012-06-12, 1391/03/23

Ethics committee reference number

391473

Health conditions studied

1

Description of health condition studied

tooth with irreversible pulpitis

ICD-10 code

k04.0

ICD-10 code description

Pulpitis: NOS acute chronic (hyperplastic)(ulcerative) irreversible reversible

Primary outcomes

1

Description

Success of the Anesthesia

Timepoint

After the Injection and during root canal therapy (RCT)

Method of measurement

Vitality pulp test (pulp tester and endo ice) before RCT and questioning from patients during RCT

2

Description

Pain

Timepoint

During injection of Anesthetic solution

Method of measurement

Heft-parker visual Analogue Scale

3

Description

Blood Pressure

Timepoint

Before and After Anesthetic injection

Method of measurement

Digital indicator -mmhg

4

Description

Onset of Anesthesia

Timepoint

After the injection with 1-minute intervals for a period of 15 minutes

Method of measurement

Vitality pulp test (pulp tester and endo ice)

5

Description

Duration of Anesthesia

Timepoint

From the beginning to the end of RCT

Method of measurement

Asking from the patients

Secondary outcomes

1

Description

Hematoma

Timepoint

One hour after the injection

Method of measurement

Observation

Intervention groups

1

Description

For the first group, primary pulpal anesthesia will provide with Intra Osseous injection of Mepivacaine 3%

Category

Treatment - Other

2

Description

For the second group, primary pulpal anesthesia will provide with Inferior Alveolar Nerve Block injection of Mepivacaine 3%

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzal dental clinic

Full name of responsible person

Razavian Seyyedhamid

Street address

Afzal dental clinic, Soroosh ave, Ahmad Abad Square, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Omid Savabi

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Vice chancellor for research, Building number 4 ,

central organ of university, Isfahan university of medical science, Hezar Jarib Ave

City

Isfahan

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, Isfahan 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

Isfahan University of Medical Sciences

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Position

Student of dentistry

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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