

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

X-tip intraosseous injection system as a primary anesthesia for irreversible pulpitis of posterior mandibular teeth

Protocol summary

Summary

Forty emergency patients with an irreversible pulpitis of mandibular posterior teeth were randomly assigned to receive either intraosseous injection using the X-tip intraosseous injection system or IAN block as primary injection method for pulpal anesthesia. Pulpal anesthetics were evaluated using an electric pulp tester and endo ice at 5-minute intervals for 15 minutes. Anesthesia's success or failure rates were recorded and final extracted data were analyzed using SPSS version 12 statistical software. $P < 0.05$ was considered significant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012110510866N1**
Registration date: **2012-11-05, 1391/08/15**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-11-05, 1391/08/15

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Treatment protocols used in this study were accepted by Dental Research Committee of Islamic Azad University of Medical Sciences, Khorasgan, Isfahan (Grant No. 821)

Expected recruitment start date

2012-09-01, 1391/06/11

Expected recruitment end date

2012-10-01, 1391/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

X-tip intraosseous injection system as a primary anesthesia for irreversible pulpitis of posterior mandibular teeth

Public title

X-tip intraosseous injection system as a primary anesthesia for irreversible pulpitis of posterior mandibular teeth

Purpose

Treatment

Inclusion/Exclusion criteria

no remarkable systemic disease e.g. cardiovascular disease, no history of taking any analgesic drugs during the past 24 hours that would alter the inflammatory response of the pulp, one mandibular posterior tooth with irreversible pulpitis.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Successful anesthesia during root canal therapy may be difficult to obtain. Intraosseous injection significantly improves anesthesia's success as a supplemental pulpal anesthesia, particularly in cases of irreversible pulpitis.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Dental Research Committee of Islamic Azad University of Medical Sciences,

Street address

Islamic Azad University of Medical Sciences, Khorasgan, Isfahan

City

Khorasgan, Isfahan

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

821

Health conditions studied

1

Description of health condition studied

Irreversible pulpitis

ICD-10 code

K04.0

ICD-10 code description

Diseases of pulp and periapical tissues

Primary outcomes

1

Description

anesthesia

Timepoint

5 min

Method of measurement

response to the cold testing and the electric pulp tester

for two sequential intervals was the definitive criterion for successful anesthesia

Secondary outcomes

empty

Intervention groups

1

Description

A single clinician performed all procedures, including diagnosis, injection, and anesthesia evaluation. For the first group, the X-tip intraosseous injection was done according to the manufacturer's instructions; after evaluating root proximity by radiography, perforation site was located in alveolar mucosa at the distal site of the first molars or at the mesial site of the second molars. A volume of (0.1 ml) 2% lidocaine with 1:100,000 epinephrine (Darou pakhsh, Tehran, Iran) was infiltrated through a 30 gauge needle at the perforation site before intraosseous injection. The perforator drill position was 90-degree angle to the cortical bone and the slow-speed hand piece was activated in a series of short bursts, using light pressure until 2 to 5 seconds had passed. The needle was then engaged in a pen-gripping fashion and 1.8 ml of 2% lidocaine with 1:100,000 epinephrine was injected slowly during 60 seconds. Before inserting the 27 gauge ultrashort X-tip needle into the guide sleeve, the needle was bent with a 60 to 80 degree angle to allow the easy insertion. The perforator was pushed through the alveolar mucosa until the X-tip faced bone.

Category

Other

2

Description

One healthy Contralateral tooth in the same jaw served as negative control and received no anesthesia and was tested by endo Ice and electric pulp tester. A single clinician performed all procedures, including diagnosis, injection, and anesthesia evaluation. In the second group, the IAN block was performed by standard technique. The IAN block group received the same type and volume of anesthetic solution.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endodontic Department of Islamic Azad University

Full name of responsible person

Dr Hamid Razavian

Street address

City

Khorasgan, Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Azad University of Khorasgan-School of Dentistry-

Full name of responsible person

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Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Azad University of Khorasgan-School of Dentistry-

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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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