

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of anesthetic efficacy of articaine as a primary injection between infiltration in the incisive/mental nerve region and inferior alveolar nerve block to treat mandibular premolar teeth with irreversible pulpitis: A, randomized, controlled, parallel, double blind study.

Protocol summary

Summary

(1) Objectives: To compare the anesthetic efficacy of 4% articaine between inferior alveolar nerve block and incisive/ mental nerve infiltration techniques during root canal treatment of mandibular premolar teeth with irreversible pulpitis. (2) Design: The study design is a randomized, controlled, parallel, double blind study. 64 participants are all adults between 18-65 years old who seek treatment for mandibular premolar teeth diagnosed with irreversible pulpitis. Patients randomly divided in to two groups. (3) Setting and conduct: one group will receive inferior alveolar nerve block(IANB) and the other incisive and mental nerve infiltration(IMNI) by a well-trained dentist. When the anesthesia Status is confirmed by the observer through using electric pulp tester, the regular root canal treatment will be initiated by the dentist. The success rate, onset/duration of anesthesia and pain intensity (from injection, during the treatment & 1 week after the treatment) of each technique will be measured and compared. (4) Participants including major eligibility criteria: Healthy patients who seek treatment for mandibular premolar teeth diagnosed with irreversible pulpitis were included; patients with systemic diseases and those are out of the range 18-65 years were excluded. (5) Intervention: Intervention group: mental/incisive injection, control group: IANB injection (6) Main outcome measures: Primary outcome: success of anesthesia, secondary outcome: the onset, duration and pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015072123278N1**

Registration date: **2016-06-01, 1395/03/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-01, 1395/03/12

Registrant information

Name

Ashraf Shubbar

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-08-31, 1394/06/09

Expected recruitment end date

2016-02-29, 1394/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of anesthetic efficacy of articaine as a primary injection between infiltration in the

incisive/mental nerve region and inferior alveolar nerve block to treat mandibular premolar teeth with irreversible pulpitis: A, randomized, controlled, parallel, double blind study.

Public title

The efficacy of articaine in mental injection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Healthy patients who seek treatment for mandibular premolar teeth diagnosed with irreversible pulpitis; patients who accept to sign the informed consent Exclusion criteria: Hematological and clotting disorders; neurological disorders; allergies to local; anesthetic drugs or sulfites; pregnancy at the time of the study; Younger than 18 year older than 65 year; patients with a history of significant medical conditions (American Society of Anesthesiologists class II or higher); clinically observed lesions or swellings at the injection site

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Permuted block randomization using sealed enveloped

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran, District 6, Pour Sina St

City

Tehran

Postal code

Approval date

2016-02-08, 1394/11/19

Ethics committee reference number

IR.TUMS.REC.1394.1906

Health conditions studied

1

Description of health condition studied

Local anesthesia

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes

1

Description

Anesthesia

Timepoint

during the root canal treatment procedure

Method of measurement

by VAS(visual analogue scale) and EPT(electric pulp tester)

Secondary outcomes

1

Description

the onset of the anesthesia

Timepoint

before starting the root canal treatment

Method of measurement

by EPT (electric pulp tester)

2

Description

the duration of anesthesia

Timepoint

time from the confirmation of anesthesia until the anesthesia subsided or the patient start to have pain again

Method of measurement

electric pulp tester and visual analogue scale

3

Description

pain

Timepoint

from injection through out the treatment and one week after the treatment

Method of measurement

visual analogue scale (VAS)

Intervention groups

1

Description

Intervention group: IMNI: incisive/mental nerve infiltration Injection will be performed with 1.8 ml of articaine 4% with 1:100,000 epinephrine (Articadent; Dentsply Pharmaceutical, York, PA, USA) between the two mandibular premolars teeth, if the second premolar is missing the injection will be distal to the first premolar apex and if the first premolar was missing the injection will be at the apex of the second premolar. After the anesthesia has been confirmed with EPT, the regular root canal treatment will be initiated. If moderate or severe pain on the basis of the values of The Heft-Parker visual analogue scale (HP-VAS) is anticipated the patient will be injected with another cartridge of 4% articaine with 1:100,000 epinephrine (Articadent; Dentsply Pharmaceutical, York, PA, USA) by the inferior alveolar block technique.

Category

Treatment - Other

2

Description

Control group: Inferior alveolar nerve block (IANB). After isolation of the teeth with cotton rolls and drying them with gauze, fluoride gel or tooth paste will be applied to the probe tip of electric pulp tester and will be placed midway between the gingival margin and the occlusal edge of the tooth that is being tested (according to the manufacturer's guidelines). Injection will be performed with 1.8 ml of 4% articaine with 1:100,000 epinephrine (Articadent; Dentsply Pharmaceutical, York, PA, USA) according to malamed technique. After the anesthesia has been confirmed with EPT, the regular root canal treatment will be initiated. If moderate or severe pain on the basis of the values of The Heft-Parker visual analogue scale (HP-VAS) is anticipated the patient will be injected with another cartridge of the same solution injection to the mental foramen region.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ashraf Shubbar

Street address

Department of Endodontics, School of Dentistry,
Kargar St, Enghelab Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Dentistry, Tehran University of Medical Sciences

Full name of responsible person

Dr. Ashraf Shubbar

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Department of Endodontics, School of Dentistry,
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Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

School of Dentistry, Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Sholeh Ghabraei

Position

Assistant Professor

Other areas of specialty/work

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Web page address**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