Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Name of organization / entity

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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 onst 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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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

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Dr. Sholeh Ghabraei

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Assistant Professor

Other areas of specialty/work

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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