Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the success rate of pulpal anesthesia in mandibular first molar following infiltration of 4% Articaine alone and as supplemental injection after inferior alveolar nerve block

Protocol summary

Summary

According to inclusion & exclusion criteria, volunteers will be selected and divided into 4 groups randomly. The clinician who does the injections will not be aware of study purpose. Also the person who does the electric pulp test (EPT); the volunteer and the statistical analyzer will not be aware of group codes. Intervention in each group will be as follow: Group 1- Inferior alveolar nerve block using 1 Lidocaine cartridge with epinephrine 1/80000. Group 2-Buccal infiltration of 1 Articaine cartridge with epinephrine 1/100000. Group 3-Buccal infiltration of 2 Articaine cartridge with epinephrine 1/100000. Group 4-Inferior alveolar nerve block using 1 Lidocaine cartridge with epinephrine 1/80000+buccal infiltration of 1 Articaine cartridge with epinephrine 1/100000. Before injection a control tooth (contralateral canine) will be tested to understand the accuracy of patient’s response to EPT; for measuring the base line vitality, each tooth will be evaluated by EPT twice. After injection each tooth will be evaluated by EPT every 3 minutes; every minute the anesthesia of lip and tongue will be checked, up to 15 minutes. If the tooth will not response to 80 degree of EPT in 2 subsequence tests, it will be discerned "completely anesthetized". Finally the information will be recorded and in addition to the success rate the mean time for onset of anesthesia and its mean duration time will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204109367N2**
Registration date: **2012-04-16, 1391/01/28**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-04-16, 1391/01/28

Registrant information

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Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences, Vce chancellor for research

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-07-22, 1391/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the success rate of pulpal anesthesia in mandibular first molar following infiltration of 4% Articaine alone and as supplemental injection after inferior alveolar nerve block

Public title
Evaluation of pulpal anesthesia with articaine
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patients aged between 18-55 years old who have at least 1 vital first mandibular molar without any restoration or decay Exclusion criteria: 1.paitients with systemic conditions which eliminate the use of epinephrine. 2.history of allergy to amide anesthetics or contents of local anesthetic cartrige. 3. pregnant women and 4. use of algesics, opioides or any other drugs which influence the anesthesia.
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Zahedan University of Medical Sciences Ethics Committee
Street address
Vice Chancellor for Research - Pardis of Zahedan University of Medical Sciences – Khalij-e-Fars Blv. – Dr. Hesabi Sq.
City
Zahedan
Postal code
98167-43463
Approval date
2011-12-19, 1390/09/28
Ethics committee reference number
90-2347

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
Success rate
Timepoint
Each 3 minutes after injection
Method of measurement
With electric pulp tester(EPT)

2

Description
Onset of anesthesia
Timepoint
Each 3 minutes after injection
Method of measurement
With electric pulp tester(EPT)

3

Description
Duration of anesthesia
Timepoint
Each 3 minutes after onset of anesthesia
Method of measurement
With electric pulp tester(EPT)

Secondary outcomes

empty

Intervention groups

1

Description
Control: Inferior alveolar nerve block using 1 Lidocaine cartridge with epinephrine 1/80000
Category
Other

2

Description
Intervention1: Buccal infiltration of 1 Articaine cartridge with epinephrine 1/100000
Category
Other

3

Description
Intervention 2: Buccal infiltration of 2 Articaine cartridge with epinephrine 1/100000
Category
Other

4

Description
Intervention 3: Inferior alveolar nerve block using 1 Lidocaine cartridge with epinephrine 1/80000+Buccal infiltration of 1 Articaine cartrdige with epinephrine 1/100000
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Endodontics, Faculty of Dentistry, Tehran University of Medical Sciences
Full name of responsible person
Dr. Kaveh Oloomi
Street address
Tehran Faculty of Dentistry, Northern Karegar St., Tehran.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences, Vice-chancellor for Research
Full name of responsible person
Mrs. Ashraf Zadeh
Street address
Pardis of Zahedan University of Medical Sciences, Khlij-e-Fars Blv., Dr. Hesabi Sq., Zahedan.
City
Zahedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan University of Medical Sciences, Vice-chancellor for Research
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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Person responsible for updating data

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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