

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the anesthetic efficacy of articaine infiltration versus lidocaine inferior alveolar nerve block in pulp therapy of lower primary molars

Protocol summary

Summary

In this study, the anesthetic efficacy of articaine infiltration technique with lidocaine infraalveolar nerve block technique in pulp therapy of lower primary molars is compared. This article is a randomized, triple-blind crossover study without control and placebo and the study group is four to ten years old healthy children who need bilateral lower primary molar pulp therapy or deep restoration. Among these, children who have good cooperation are included, but children who do not cooperate are excluded and For this purpose, 64 children are enrolled in the study. Children are randomly and equally divided into two groups, A and B and they are treated within two sessions and in each session, one lower primary molar pulp therapy is done. Group A, in first session receives lidocaine infraalveolar nerve block injection and in second session receives articaine infiltration injection. In group B, all the procedure is the same as group A, but this group in first session receives articaine infiltration injection and in second session receives lidocaine infraalveolar nerve block injection. Also the washout period is one week. In each session, at the moment of pulp exposure, the child will be asked to mark visual analogue scale according to his pain. If the anesthesia caused by articaine infiltration injection is equal or better than lidocaine infraalveolar nerve block injection, due to greater ease and lesser risk, it can be the choice injection in pulp therapy of lower primary molars.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102830448N2**

Registration date: **2016-11-14, 1395/08/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-11-14, 1395/08/24

Registrant information

Name

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Name of organization / entity

Rafsanjan university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the anesthetic efficacy of articaine infiltration versus lidocaine inferior alveolar nerve block in pulp therapy of lower primary molars

Public title

Comparison of the anesthetic efficacy of two techniques

in pulp therapy of lower primary molars

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion: 4-10 years old children who are healthy and have good cooperation and need bilateral lower primary molar pulp therapy or deep restorations. Exclusion: Children who do not cooperate or have a history of medical problems for local anesthesia or have a wound or mucousal lesions in the buccal vestibule

Age
From **4 years** old to **10 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Rafsanjan University of Medical Sciences

Street address
Dental school, west Mofateh avenue

City
Rafsanjan

Postal code

Approval date
2016-10-24, 1395/08/03

Ethics committee reference number
ir.rums.rec.1395.76

Health conditions studied

1

Description of health condition studied
Local anaesthesia

ICD-10 code
Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes

1

Description
pain

Timepoint
one week

Method of measurement
visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Articaine , infiltration, 4% , injection

Category
Treatment - Drugs

2

Description
lidocaine , infraalveolar nerve block injection , 2 % , injection

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental school of Rafsanjan

Full name of responsible person
Dr Maryam Sharifi

Street address
West Mofateh avenue

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Rafsanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences

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Rafsanjan

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

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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