

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of pain reduction between lidocaine and articaine for anesthesia of the second primary molar, requiring pulp therapy, a Randomized Clinical Trial.

Protocol summary

Summary

Objectives: comparison of the pain perception and onset time of anesthesia between lidocaine and articaine for local anesthesia of the maxillary molar. Double blind Randomized Clinical Trial among 130 subjects admitted to dental clinic of Qazvin University of Medical Sciences. All subjects will be divided into two groups and individuals in each group will receive lidocaine or articaine for local anesthesia. Either lidocaine or articaine will be named as A or B and will be placed in a bottle. The drug will be given to another researcher for injection. Injection will be done randomly. Another researcher will measure pain perception during injection using visual analogue pain scale and the onset time of anesthesia in 1 minute intervals until complete anesthesia. All data will be saved for each subject. Inclusion criteria: volunteers requiring pulp therapy with intact maxillary molar that response to pulp tester; individuals who can use visual analogue pain scale. Exclusion criteria: patients with periodontal disease; positive history of alcohol consumption; cigarette smoking; drug user; patients who have received antidepressant or steroid analogues drug during the 48 hours before study; pregnant patients; patients with known allergy to lidocaine or epinephrine; peripheral neuropathy, positive history of dental phobia or any damage to teeth. Interventions included in Infiltrative injection of 4% articaine carpule with epinephrine 1:100000 in the maxillary molar as group of cases, including 65 cases and 2% lidocaine carpule with epinephrine 1:100000 in the maxillary molar as control group, including 65 cases and measuring of pain perception at the time of injection by using visual analogue pain scale and onset time of anesthesia in one-minute intervals until a complete anesthesia. Primary outcome is onset time of anesthesia and Secondary outcome is Severity of pain during injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062627111N2**

Registration date: **2016-08-21, 1395/05/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-21, 1395/05/31

Registrant information

Name

Farshid Rayati

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Qazvin University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pain reduction between lidocaine and articaine for anesthesia of the second primary molar, requiring pulp therapy, a Randomized Clinical Trial.

Public title

Comparison of pain reduction between lidocaine and articaine for anesthesia in extraction of molar teeth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: volunteers requiring pulp therapy with intact maxillary molar that response to pulp tester; individuals who can use visual analogue pain scale. Exclusion criteria: patients with periodontal disease; positive history of alcohol consumption; cigarette smoking; drug user; patients who have received antidepressant or steroid analogues drug during the 48 hours before study; pregnant patients; patients with known allergy to lidocaine or epinephrine; peripheral neuropathy, positive history of dental phobia or any damage to teeth

AgeFrom **21 years** old to **60 years** old**Gender**

Both

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **130****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization will be done by closed envelopes method. lidocaine or articaine for local anesthesia. Either lidocaine or articaine will be named as A or B and will be placed in a bottle. The drug will be given to another researcher for injection. Injection will be done randomly.

Secondary Ids

empty

Ethics committees1**Ethics committee**

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Shahid Bahonar Blvd.

City

Qazvin

Postal code**Approval date**

2016-03-09, 1394/12/19

Ethics committee reference number

Ir.QUMS.REC.1394.820

Health conditions studied1**Description of health condition studied**

Local Anesthesia

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes1**Description**

onset time of anesthesia

Timepoint

1 minute intervals

Method of measurement

Patient Self Recall

Secondary outcomes1**Description**

Severity of pain during injection

Timepoint

Immediately after the injection

Method of measurement

Visual analogue pain scale

Intervention groups1**Description**

Infiltrative injection of 4% articaine carpule with epinephrine 1:100000 and measuring of pain perception at the time of injection by using visual analogue pain scale and onset time of anesthesia in one-minute intervals until a complete anesthesia

Category

Treatment - Drugs

2**Description**

Infiltrative injection of 2% lidocaine carpule with epinephrine 1:100000 and measuring of pain perception at the time of injection by using visual analogue pain scale in one-minute intervals by using electric pulp test until a complete anesthesia

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Oral and maxillofacial surgery Unit of Qazvin
Dentistry Faculty

Full name of responsible person

Farshid Raity,MD

Street address

Oral and maxillofacial surgery Unit, Dentistry Faculty
of Qazvin University of Medical Sciences, Bahonar
Blvd.

City

Qazvin

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Qazvin University of
Medical Sciences

Full name of responsible person

Amin Peymani, MD.

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Qazvin University of Medical Sciences, Bahonar Blvd.

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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

Vice Chancellor for Research, Qazvin 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**

Qazvin University of Medical Sciences

Full name of responsible person

Farshid Rayati

Position

Oral and maxillofacial Surgery Specialist

Other areas of specialty/work**Street address**

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City

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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