

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of pain perception and onset time of anesthesia between lidocaine and articaine for local anesthesia of the maxillary central incisor in healthy subjects: a randomized, double blind crossover trial

Protocol summary

Summary

The aim of this randomized cross over double blind clinical trial is to compare the pain perception and onset time of anesthesia between lidocaine and articaine for local anesthesia of the maxillary central incisor. This study will be performed among 16 healthy subjects who come to dental clinic of Hormozgan University of Medical Sciences. Inclusion criteria containing healthy volunteers with intact maxillary central incisor that response to pulp test; individuals who can use visual analogue pain scale. Exclusion criteria containing 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. All subjects will divided into two groups and individuals in each group will received lidocaine or articaine for local anesthesia of maxillary central incisor. 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. 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 by electric pulp test. All data will be saved for each subject and after 2 week interval, the intervention will be replace with another option for anesthesia induction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110613932N3**
Registration date: **2016-06-19, 1395/03/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-19, 1395/03/30

Registrant information

Name

Seyed Shojaeddin Namazi

Name of organization / entity

Hormozgan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 74 1333 4190

Email address

ssh.namazi@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Hormozgan University of Medical Sciences

Expected recruitment start date

2016-02-21, 1394/12/02

Expected recruitment end date

2016-04-21, 1395/02/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pain perception and onset time of anesthesia between lidocaine and articaine for local

anesthesia of the maxillary central incisor in healthy subjects: a randomized, double blind crossover trial

HUMS.REC.1394.86

Public title

comparison of anesthetic effect between lidocaine and articain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: healthy volunteers with intact maxillary central incisor 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

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: 16

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Hormozgan University of Medical Sciences

Street address

Research Counsil Building, Shahid Mohammadi Hospital, jomhoori Eslami Blvd

City

Bandar Abbas

Postal code

Approval date

2015-09-23, 1394/07/01

Ethics committee reference number

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

onset time of anesthesia

Timepoint

1 minute intervals

Method of measurement

Electric Pulp Test

2

Description

Severity of pain during injection

Timepoint

Immediately after the injection

Method of measurement

Visual analogue pain scale

Secondary outcomes

empty

Intervention groups

1

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 and onset time of anesthesia in one-minute intervals by using electric pulp test until a complete anesthesia

Category

Other

2

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 by using electric pulp test until a complete anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

dental clinic of hormozgan university of medical sciences

Full name of responsible person

Rokhsare Zare Shahri

Street address**City**

Bandar Abbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Hormozgan University of Medical Sciences

Full name of responsible person

Abdolazim Nejatizadeh

Street address

Research Council Building, Shahid Mohammadi Hospital, Jomhoori Eslami Blvd

City

Bandar Abbas

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, Hormozgan 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**

Student Research Committee

Full name of responsible person

Rokhsare Zare Shahri

Position

Dental Student

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

Dental Clinic of Hormozgan University of Medical Sciences, Shariati Hospital, Shahid Naser Blvd

City

Bandar Abbas

Postal code**Phone**

+98 76 3333 0521

Fax**Email**

mahtab_137@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Student Research Committee

Full name of responsible person

Rokhsare Zare Shahri

Position

Dental Student

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

Dental Clinic, Shariati Hospital, Shahid Naser Blvd

City

Bandar Abbas

Postal code**Phone**

+98 76 3333 0521

Fax**Email**

mahtab_137@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Student Research Committee

Full name of responsible person

Rokhsare Zare Shahri

Position

Dental Student

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

Dental Clinic, Shariati Hospital, Shahid Naser Blvd

City

Bandar Abbas

Postal code**Phone**

+98 76 3333 0521

Fax**Email**

mahtab_137@yahoo.com

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