Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of anesthetic efficacy of articaine with lidocaine as an inferior nerve blocking agent in subjects with symptomatic irreversible pulpitis

Protocol summary

Study aim

To compare the anesthetic efficacy of articaine with lidocaine as an inferior nerve blocking agent in subjects with symptomatic irreversible pulpitis.

Design

Two arm, parallel group, double blind randomised control trial

Settings and conduct

Eligible subjects reporting to department of Operative Dentistry, Islamic International Dental Hospital (IIDH), Islamabad, during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through randomization software. This trial will be double-blinded so that neither patients nor the physician examining the patients will be aware of the anesthetic solution used.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Subjects of both genders, in good health, with no systemic disease that will interfere with the action of any of the anesthetic solutions being used, aged between 26 – 35 years. Mandibular posterior teeth requiring endodontic treatment due to symptomatic irreversible pulpitis, with no previous attempts of endodontic therapy on that tooth, positive to pulp sensibility testing (cold testing). Exclusion Criteria: Patients who have known allergy to amides or are taking any medication that will alter their perception of pain, patients suffering from any heart disease, diabetes mellitus, female patients who are pregnant.

Intervention groups

Intervention group: subjects receiving articaine (1.7 ml of Septanest SP 4% articaine with 1:100,000 epinephrine each) as inferior nerve blocking agent Control group: subjects receiving lidocaine (1.7 ml of Lignospan standard 2% lidocaine with 1:100,000 epinephrine each) as inferior nerve blocking agent

Main outcome variables

Pain relief after anesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211230053569N1**
Registration date: **2023-04-11, 1402/01/22**
Registration timing: **retrospective**

Last update: **2023-04-11, 1402/01/22**
Update count: **0**

Registration date

2023-04-11, 1402/01/22

Registrant information

Name
Sobia Hassan
Name of organization / entity
Riphah International University, Islamabad
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Pakistan
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-01, 1401/05/10

Expected recruitment end date

2022-08-30, 1401/06/08

Actual recruitment start date

2022-08-01, 1401/05/10

Actual recruitment end date

2022-08-30, 1401/06/08

Trial completion date

2022-08-30, 1401/06/08

Scientific title

Comparison of anesthetic efficacy of articaine with lidocaine as an inferior nerve blocking agent in subjects with symptomatic irreversible pulpitis

Public title

Anesthetic efficacy of articaine with lidocaine in symptomatic irreversible pulpitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Subjects of both genders (males and females), in good health, with no systemic disease that will interfere with the action of any of the anesthetic solutions being used, aged between 26 – 35 years Mandibular posterior teeth requiring endodontic treatment due to symptomatic irreversible pulpitis There should have been no previous attempts of endodontic therapy on that tooth Positive pulp sensibility testing (cold testing)

Exclusion criteria:

Patients who have known allergy to amides Patients taking any medication that will alter their perception of pain Patients who are suffering from any heart disease, diabetes mellitus Female patients who are pregnant

Age

From **26 years** old to **35 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **152**

Actual sample size reached: **152**

Randomization (investigator's opinion)

Randomized

Randomization description

Before the experiment, each of the two anesthetic solutions will be labeled as A and B. Simple, individual randomization will be done and subjects will be randomly allocated either solution A or B, using online randomization software (OpenEpi)

Blinding (investigator's opinion)

Double blinded

Blinding description

Before the experiment, each of the two anesthetic solutions will be covered to conceal the name of the product and labeled as A and B respectively. Both the chief researcher and the patient will be unaware of which alphabet represents which solution.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic International Dental College

Street address

Street 41, off 7th Avenue, G-7/4

City

Islamabad

Postal code

44000

Approval date

2020-01-01, 1398/10/11

Ethics committee reference number

IIDC/IRC/2020/001/012

Health conditions studied

1

Description of health condition studied

Symptomatic irreversible pulpitis in posterior mandibular teeth

ICD-10 code

K04.02

ICD-10 code description

Irreversible pulpitis

Primary outcomes

1

Description

Pain relief after anesthesia

Timepoint

Immediately after intervention

Method of measurement

Visual Analogue Scale for pain assessment

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: subjects diagnosed with symptomatic irreversible pulpitis (after taking history, carrying out cold testing and filling the Visual Analogue Scale to score

pain levels) receiving 1.7 ml of 4% articaine with 1:100,000 epinephrine (Septanest SP) as inferior nerve blocking agent.

Category

Treatment - Drugs

2

Description

Control group: subjects diagnosed with symptomatic irreversible pulpitis (after taking history, carrying out cold testing and filling the Visual Analogue Scale to score pain levels) receiving 1.7 ml of 2% lidocaine with 1:100,000 epinephrine (Lignospan standard), as inferior nerve blocking agent.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Islamic International Dental College

Full name of responsible person
Dr Sobia Bostan

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Sponsors / Funding sources

1

Sponsor

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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

Riphah International University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Riphah International University

Full name of responsible person
Dr Sobia Hassan

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available