

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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

##### Country

Pakistan

##### Phone

+92 51 2890690

##### Email address

sobiabostan@gmail.com

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

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sobia.hassan@riphah.edu.pk

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

Riphah International University

**Full name of responsible person**

Dr Sobia Hassan

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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 scientific 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**

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## Person responsible for updating data

### 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**  
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**Province**  
ICT  
**Postal code**  
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**Phone**

## 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