

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Comparison of buffered with standard local anesthetics in odontogenic infections: a randomized controlled trial

#### Protocol summary

##### Study aim

To compare the efficacy of buffered local anesthetic with non-buffered local anesthetic in terms of pain reduction and speed of onset of anesthesia.

##### Design

It was a randomized, parallel group, double blinded, single center study including 100 patients in total.

##### Settings and conduct

This randomized controlled trial was conducted at Armed Forces Institute of Dentistry in the outpatient department of Oral & Maxillofacial Surgery from March 2020 to Dec 2022.

##### Participants/Inclusion and exclusion criteria

The physical condition of all patients was evaluated, and those with systemic diseases for which injections of lignocaine with adrenaline were contraindicated, were excluded from the study.

##### Intervention groups

The study included a total of 140 TMD patients that were randomly assigned to two groups: Buffered Group (A) (n=50) and Non- Buffered Group or Control Group (B) (n=50). Buffered local anesthesia was made by adding 0.18 ml of 8.4% solution of sodium bicarbonate to a 1.8ml cartridge of 2% Lignocaine with adrenaline 1:100,000 leading to a 1:10 dilution. All procedures were done by a single maxillofacial surgeon, who was unaware of the type of LA given to the patient.

##### Main outcome variables

Pain intensity was assessed using the Visual Analog Scale (VAS) and speed of onset of anesthesia measured in seconds from point of retrieval of the needle.

#### General information

##### Reason for update

The dates have been updated.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230622058557N2**

Registration date: **2023-07-04, 1402/04/13**

Registration timing: **retrospective**

Last update: **2023-12-20, 1402/09/29**

Update count: **1**

##### Registration date

2023-07-04, 1402/04/13

##### Registrant information

###### Name

Syeda Mahnoor Fatima

###### Name of organization / entity

National University of Medical Sciences

###### Country

Pakistan

###### Phone

+92 335 5508126

###### Email address

mahnoorbukhari@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-11, 1397/12/20

##### Expected recruitment end date

2023-01-31, 1401/11/11

##### Actual recruitment start date

2019-08-01, 1398/05/10

##### Actual recruitment end date

2023-03-31, 1402/01/11

##### Trial completion date

2023-04-30, 1402/02/10

##### Scientific title

Comparison of buffered with standard local anesthetics in odontogenic infections: a randomized controlled trial

##### Public title

Effect of buffered anesthetics in odontogenic infections

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patient between 18 to 70 years that have Odontogenic maxillofacial infection surrounding any tooth. Lack of sensitivity to local anesthetics Patients having acute abscess of any tooth Patients having acute periapical periodontitis leading to granuloma formation Patients having physical status 1 and 2 according to American Society of Anesthesiologists(ASA) classification

### Exclusion criteria:

Patients with systemic diseases for which injections of lignocaine with adrenaline are contraindicated will be excluded from the study Anesthesia allergy or drug abuse history

## Age

From **18 years** old to **70 years** old

## Gender

Both

## Phase

4

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **70**

Actual sample size reached: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization was performed using a sealed envelope with a computer-generated random allocation for each patient. According to the this, patients were randomly divided to receive either be in the Buffered Group (A) or Non Buffered Group (B).

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Double-blind fashion technique was used in which the patient is unaware of the type of anesthetic being administered to them , buffered or standard and the Doctor administering the local anesthesia doesn't know if the cartridge has been buffered or not. It was prepared by another researcher and handed to the doctor administering the injection.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics Committee- Armed Forces Institute of Dentistry

#### Street address

AFID, CMH, Rawalpindi

#### City

Rawalpindi

#### Postal code

46000

### Approval date

2020-03-09, 1398/12/19

### Ethics committee reference number

Ref:905/Trg-ABP1K3

## Health conditions studied

## 1

### Description of health condition studied

Odontogenic Infection: Defined as inflammation originating within a tooth or closely related to the surrounding structures presenting as periapical inflammation in the form of acute periapical periodontitis or a periapical abscess with or without extensions into adjacent facial planes.

### ICD-10 code

K04.7

### ICD-10 code description

Periapical abscess without sinus

## 2

### Description of health condition studied

Odontogenic Infection: Defined as inflammation originating within a tooth or closely related to the surrounding structures presenting as periapical inflammation in the form of acute periapical periodontitis or a periapical abscess with or without extensions into adjacent facial planes.

### ICD-10 code

K04.4

### ICD-10 code description

Acute apical periodontitis of pulpal origin

## Primary outcomes

## 1

### Description

Pain Assessment: Pain will be determined by the patient before and after injection using VAS Pain score. It is a 10 cm long scale with 0 marking indicating no pain to 10 marking as worst pain possible.

### Timepoint

Before and immediately after local anesthetic injection.

### Method of measurement

Visual Analog Pain Score

**2**

**Description**

Efficacy of Anesthesia: Determined by the onset of anesthesia i.e. the first feeling of numbness in the region of the teeth anaesthetized checked by inserting straight probe in the gingival sulcus of the involved region.

**Timepoint**

Immediately after injection is administered with 30 seconds intervals .

**Method of measurement**

Seconds

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Group A. This group received buffered local anesthesia by adding 0.18 ml of 8.4 percent sodium bicarbonate solution to 1.8ml 2 % Lignocaine with 1:100,000 adrenaline cartridge immediately before injecting.

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: Group B. This group will receive standard 2 % Lignocaine with 1:100,000 adrenaline cartridge that has not been buffered.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Armed Forces Institute of Dentistry

**Full name of responsible person**

Dr. Syeda Mahnoor Fatima

**Street address**

AFID, Combined Military Hospital, Rawalpindi

**City**

Rawalpindi

**Postal code**

46000

**Phone**

+92 51 8314500

**Email**

mahnoorbukhari@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Armed Forces Institute of Dentistry

**Full name of responsible person**

Syeda Mahnoor Fatima

**Street address**

AFID, CMH, Rawalpindi

**City**

Rawalpindi

**Postal code**

46000

**Phone**

+92 335 5508126

**Email**

mahnoorbukhari@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Armed Forces Institute of Dentistry

**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**

Other

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Armed Forces Institute of Dentistry affiliated with National University of Medical Sciences

**Full name of responsible person**

Syeda Mahnoor Fatima

**Position**

Senior Registrar

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

AFID,CMH, Rawalpindi

**City**

Rawalpindi

**Province**

Punjab

**Postal code**

46000

**Phone**

+92 335 5508126

**Email**

mahnoorbukhari@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Combined Military Hospital

**Full name of responsible person**

Zahra Saeed

**Position**

Senior Registrar

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

CMH, Lahore

**City**

Lahore

**Province**

Punjab

**Postal code**

54810

**Phone**

+92 343 9853049

**Email**

zahra.saeed15@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Armed Forces Institute of Dentistry

**Full name of responsible person**

Syeda Soveba Zaidi

**Position**

Registrar

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

AFID, CMH, Rawalpindi

**City**

Rawalpindi

**Province**

Punjab

**Postal code**

46000

**Phone**

+92 334 0112305

**Email**

sovebazaidi@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

It is the organization's policy to not share IPD

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is 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

**Title and more details about the data/document**

The data is entered in SPSS Software.

**When the data will become available and for how long**

6 months after publication for a period of 3 months.

**To whom data/document is available**

To Medical and Dental Academic Institutes.

**Under which criteria data/document could be used**

Academic professionals studying in Medical & Dental Institutes.

**From where data/document is obtainable**

Email to Investigator.

**What processes are involved for a request to access data/document**

Email to Investigator.

**Comments**