

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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+92 335 5508126

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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

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AFID, Combined Military Hospital, Rawalpindi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Armed Forces Institute of Dentistry

Full name of responsible person

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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

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

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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