Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Pakistan

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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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Sponsors / Funding sources

1

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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
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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