

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of Single Buccal Infiltration Versus Conventional Buccal and Palatal Infiltration for Maxillary Tooth Extraction

Protocol summary

Study aim

To compare the effectiveness of 2% Lidocaine Hydrochloride injection containing 1:100,000 Epinephrine administered as a single buccal infiltration versus conventional buccal and palatal infiltration during maxillary tooth extraction, using pain scores during injection and extraction as outcome measures.

Design

consecutive non-random sampling, single centre

Settings and conduct

armed Forces Institute of dentistry, CMH,Rawalpindi, pakistan

Participants/Inclusion and exclusion criteria

INCLUSION CRITERIA: Patients presented to Oral and Maxillofacial surgery for any maxillary tooth removal for reasons like non-restorable tooth due to extensive caries or periodontal disease or for orthodontic extractions and assessed as suitable for removal under local anaesthesia. 2. Patients between the age of 18 and 45 years who were fit for the procedure. 3. Either gender. 4. Patients having physical status 1 according to American Society of Anesthesiologists (ASA) classification. **EXCLUSION CRITERIA:** 1. Pregnant women, nursing mothers. 2. Patient with non-localized odontogenic infection. 3. Tooth associated with pathologies i.e. cysts, fractures, tumors. 4. Patients on radiotherapy, chemotherapy, bisphosphonates, bone diseases e.g. Paget's disease.

Intervention groups

two intervention groups: Group A — received a single buccal infiltration only (2 mL, 2% lidocaine HCl with 1:100,000 epinephrine) Group B — received the conventional buccal + palatal infiltration (1.75 mL buccal + 0.25 mL palatal, same anesthetic)

Main outcome variables

Primary outcome: pain intensity (VAS score) measured after local anesthetic injection and after tooth extraction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230714058773N6**

Registration date: **2026-08-06, 1405/05/15**

Registration timing: **retrospective**

Last update: **2026-08-06, 1405/05/15**

Update count: **0**

Registration date

2026-08-06, 1405/05/15

Registrant information

Name

Tehmina Maryam

Name of organization / entity

Armed forces institute of dentistry, combined military hospital, Rawalpindi, Pakistan

Country

Pakistan

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+92 333 9576737

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-08-20, 1403/05/30

Actual recruitment start date

2024-02-20, 1402/12/01

Actual recruitment end date

2024-08-20, 1403/05/30

Trial completion date

2024-08-20, 1403/05/30

Scientific title

Comparison of Single Buccal Infiltration Versus Conventional Buccal and Palatal Infiltration for Maxillary Tooth Extraction

Public title

Comparison of Single Buccal Infiltration Versus Conventional Buccal and Palatal Infiltration for Maxillary Tooth Extraction

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients presented to Oral and Maxillofacial surgery for any maxillary tooth removal for reasons like non-restorable tooth due to extensive caries or periodontal disease or for orthodontic extractions and assessed as suitable for removal under local anaesthesia. Patients between the age of 18 and 45 years who were fit for the procedure. Either gender. Patients having physical status 1 according to American Society of Anesthesiologists (ASA) classification.

Exclusion criteria:

Pregnant women, nursing mothers. Patient with non-localized odontogenic infection. Tooth associated with pathologies i.e. cysts, fractures, tumors. Patients on radiotherapy, chemotherapy, bisphosphonates, bone diseases e.g. Paget's disease

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **260**

Actual sample size reached: **260**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients meeting the inclusion criteria were randomised into Group A (single buccal infiltration) or Group B (conventional buccal and palatal infiltration) using the lottery method. Equal numbers of folded paper chits marked "A" and "B" were prepared, corresponding to the total planned sample size, and placed in a sealed opaque container. At the time of enrolment, after the patient had provided informed consent, one chit was drawn by a staff member not involved in performing the extraction, and the patient was allocated to the group indicated on the chit. Each chit was discarded after use so that it could not be redrawn, ensuring that every patient had an equal and independent chance of allocation to either group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Armed Forces Institute of Dentistry, Combined Military Hospital, Rawalpindi

Street address

Armed Forces Institute of Dentistry, Combined Military Hospital, Rawalpindi

City

Rawalpindi

Postal code

46000

Approval date

2024-02-15, 1402/11/26

Ethics committee reference number

905/Trg-ABP1K2

Health conditions studied

1

Description of health condition studied

Need for maxillary tooth extraction (due to non-restorable caries, periodontal disease, or orthodontic indication)

ICD-10 code

maxillary

ICD-10 code description

maxillary tooth extraction

Primary outcomes

1

Description

Pain

Timepoint

10 minutes after injection and immediately after extraction

Method of measurement

visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: single buccal infiltration (2 mL, 2% lidocaine HCl with 1:100,000 epinephrine)

Category

Other

2**Description**

Control group: conventional buccal + palatal infiltration (1.75 mL buccal + 0.25 mL palatal, same anesthetic)

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Armed Forces Institute of Dentistry, Combined Military Hospital, Rawalpindi

Full name of responsible person

Dr Tehmina Maryam

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

Armed Forces Institute of Dentistry, Combined Military Hospital, Rawalpindi

Full name of responsible person

Dr Raeha Nadeem

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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, Combined Military Hospital, Rawalpindi

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**

Armed Forces Institute of Dentistry, Combined Military Hospital, Rawalpindi

Full name of responsible person

Dr Tehmina Maryam

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Oral and Maxillofacial Surgery

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Dr Noman Tahir

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

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Comparison of Single Buccal Infiltration Versus
Conventional Buccal and Palatal Infiltration for Maxillary
Tooth Extraction

When the data will become available and for how long

after publication for good

To whom data/document is available

everyone

Under which criteria data/document could be used

everyone

From where data/document is obtainable

tehminamaryam27@gmail.com

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

Researchers interested in accessing the de-identified dataset and/or data collection forms may submit a written request to the corresponding author, along with a brief description of the intended use. Requests will be reviewed and, upon approval from the Department of Oral and Maxillofacial Surgery, AFID Rawalpindi, the relevant data will be shared within few weeks of the request. Data will be provided in pdf file and will exclude any patient-identifying information in line with the informed consent obtained from participants.

Comments