Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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