

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison between the Use of Only Buccal Infiltration and with palatal infiltration Of 2% Lidocaine with Epinephrine for The Removal of Maxillary Teeth

#### Protocol summary

##### Study aim

Aim of study was to evaluate effectiveness of use of single buccal infiltration and conventional two pricks of buccal and palatal injections in terms of providing equally effective analgesia for maxillary tooth extractions, at the same time causing less pain due to single injection rather than conventional two pricks method.

##### Design

Consecutive non random sampling with a parallel group design of 260 patients enrolled between 20th Feb 2021 to 20th Aug 2021 and followed for 6 months

##### Settings and conduct

Department of Oral and Maxillofacial Surgery, AFID Rawalpindi

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age of 18-45 years, non-restorable tooth due to extensive caries or periodontal disease or for orthodontic extractions, physical status 1 according to ASA Exclusion criteria: Tooth associated with pathologies, non-odontogenic infections, patients on chemotherapy, radiotherapy and bisphosphonates

##### Intervention groups

Before administration of the local anaesthetic agent, each patient was instructed on the Visual Analog Scale (VAS) by a dental assistant. Patients were receive infiltration of 2 mL (2% lidocaine HCl with 1:100,000 epinephrine) in the mucobuccal fold adjacent to tooth, at a slow rate of administration, over approximately 1 minute under aseptic technique.

##### Main outcome variables

The minimum VAS pain score in control group after LA Injection, was 18 and maximum VAS pain score was 34 with mean and standard deviation as  $26.78 \pm 4.993$  and After tooth extraction, was 7 and maximum VAS pain score was 23 with mean and standard deviation as  $14.18 \pm 4.890$ . The minimum VAS pain score in intervention

group after LA Injection, was 31 and maximum VAS pain score was 45 with mean and standard deviation as  $38.14 \pm 4.372$ , after tooth extraction, was 7 and maximum VAS pain score was 19 with mean and standard deviation as  $13.33 \pm 3.595$

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230714058773N3**

Registration date: **2023-09-11, 1402/06/20**

Registration timing: **retrospective**

Last update: **2023-09-11, 1402/06/20**

Update count: **0**

##### Registration date

2023-09-11, 1402/06/20

##### Registrant information

##### Name

Tehmina Maryam

##### Name of organization / entity

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

##### Country

Pakistan

##### Phone

+92 333 9576737

##### Email address

tehminamaryam@hotmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-02-20, 1398/12/01

**Expected recruitment end date**

2020-08-20, 1399/05/30

**Actual recruitment start date**

2020-02-20, 1398/12/01

**Actual recruitment end date**

2020-08-20, 1399/05/30

**Trial completion date**

2020-08-20, 1399/05/30

**Scientific title**

Comparison between the Use of Only Buccal Infiltration and with palatal infiltration Of 2% Lidocaine with Epinephrine for The Removal of Maxillary Teeth

**Public title**

Comparison between the Use of Only Buccal Infiltration and with palatal infiltration Of 2% Lidocaine with Epinephrine for The Removal of Maxillary Teeth

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

non-restorable tooth due to extensive caries or periodontal disease or for orthodontic extractions Patients between the age of 18 and 45 years 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)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of armed forces institute of dentistry CMH Rawalpindi

**Street address**

Range road Rawalpindi

**City**

Rawalpindi

**Postal code**

46000

**Approval date**

2021-01-30, 1399/11/11

**Ethics committee reference number**

905/Trg-ABP1K2

**Health conditions studied****1****Description of health condition studied**

Buccal Infiltration, Palatal infiltration, Maxillary Teeth

**ICD-10 code**

Y48.3

**ICD-10 code description**

Local anaesthetics

**Primary outcomes****1****Description**

Pain

**Timepoint**

10 minutes After infiltration of local anesthesia and immediately after extraction

**Method of measurement**

10 point Visual Analog Scale as None, Weak, Moderate and Severe pain . If VAS  $\geq$  7 then it was considered pain

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: 130 patients were selected according to inclusion criteria. Before administration of the local anaesthetic agent, each patient was instructed on the Visual Analog Scale (VAS) by a dental assistant. Patients were receive infiltration of 2 mL (2% lidocaine HCl with 1:100,000 epinephrine) in the mucobuccal fold adjacent to tooth, at a slow rate of administration, over approximately 1 minute under aseptic technique. Then, extraction was performed after the wait of 10 minutes in all the patients . During the latency period, patients were

complete the VAS as their own control, to score on the 10 points Visual analog scale, to record the amount of pain they get experience on injection. Immediately after extraction, patients later on was asked again to record the experienced pain intensity during the extraction on data collection form on 10 points Visual Analog Scale (VAS).

#### Category

Treatment - Surgery

## 2

#### Description

Control group: 130 patients were selected according to inclusion criteria Before administration of the local anaesthetic agent, each patient was instructed on the Visual Analog Scale (VAS) by a dental assistant. Patients were receive infiltration of 2 mL (2% lidocaine HCl with 1:100,000 epinephrine in the mucobuccal fold adjacent to tooth and 0.25 mL infiltration palatally at a slow rate of administration, over approximately 1 minute under aseptic technique. Then, extraction was performed after the wait of 10 minutes in all the patients . During the latency period, patients were complete the VAS as their own control, to score on the 10 points Visual analog scale, to record the amount of pain they get experience on injection. For extraction, elevation and forced techniques were used but with minimal reflection of palatal gingiva. Immediately after extraction, patients later on was asked again to record the experienced pain intensity during the extraction on data collection form on 10 points Visual Analog Scale (VAS).

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Armed forces institute of dentistry CMH ,Rawalpindi ,Pakistan

##### Full name of responsible person

Tehmina Maryam

##### Street address

Range road Rawalpindi

##### City

Rawalpindi

##### Postal code

46000

##### Phone

+92 333 9576737

##### Email

tehminamaryam27@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Armed forces institute of dentistry CMH Rawalpindi

#### Full name of responsible person

Nazir Khan

#### Street address

Range road Rawalpindi

#### City

Rawalpindi

#### Postal code

46000

#### Phone

+92 333 2353267

#### Email

nazeerkhan996@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 CMH 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, Pakistan

##### Full name of responsible person

Tehmina Maryam

##### Position

Final year registrar

##### Latest degree

Bachelor

##### Other areas of specialty/work

Oral and maxillofacial surgery

##### Street address

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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

**Full name of responsible person**

Tehmina Maryam

**Position**

Final year registrar

**Latest degree**

Bachelor

**Other areas of specialty/work**

Oral and maxillofacial surgery

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Armed forces institute of dentistry CMH Rawalpindi

**Full name of responsible person**

Tehmina Maryam

**Position**

Registrar

**Latest degree**

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**Other areas of specialty/work**

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**Street address**

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**Postal code**

46000

**Phone**

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**Email**

Tehminamaryam27@gmail.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**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not 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**

No - There is not a plan to make this available