

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 ± 4.993 and After tooth extraction, was 7 and maximum VAS pain score was 23 with mean and standard deviation as 14.18 ± 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 ± 4.372 , after tooth extraction, was 7 and maximum VAS pain score was 19 with mean and standard deviation as 13.33 ± 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

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+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

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46000

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Email

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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

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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 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

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Tehmina Maryam

Position

Final year registrar

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

Bachelor

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

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