Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 crieteria: 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 crieteria: 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

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 ≥ 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

AMC officers mess opposite to AFIMH gate no 5 abid majeed road Rawalpindi

City

Rawalpindi

Province

Punjab

Postal code

46000

Phone

+92 333 9576737

Fax

Email

tehminamaryam@hotmail.com

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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AMC officers mess opposite to AFIMH gate no 5 abid majeed road Rawalpindi

City
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Province
Punjab

Postal code
46000

Phone
+92 333 9576737

Fax

Email
tehminamaryam@hotmail.com

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
Bachelor

Other areas of specialty/work
Oral and maxillofacial surgery

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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