

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Soft Tissue Healing in Immediate Implant Placement in Fresh Extraction Socket with and without the Use of Platelet-Rich Fibrin

Protocol summary

Study aim

To compare soft tissue healing regarding cover screw exposure on 7th post op day and pink esthetic score on 3rd and 6th post op month in immediate implant placement in fresh extraction socket with and without the use of platelet rich fibrin.

Design

A Prospective, Randomized Controlled clinical trial with a parallel group design of 60 patients, enrolled between 20th January 2021 to 19th October 2021 and followed for 8 months

Settings and conduct

Department of Oral and Maxillofacial Surgery, AFID Rawalpindi.

Participants/Inclusion and exclusion criteria

Inclusion criteria: min age 18-60 years old, presence of Maxillary and mandibular teeth without active infection, with healthy surrounding tissue Exclusion criteria: edentulous patients, patients having diabetes, undergoing chemotherapy, radiotherapy, habit of smoking

Intervention groups

Intervention group shows stimulation and acceleration of bone regeneration and show tendency toward rapid soft tissue regeneration and reduced peri-implant pain and inflammation as compared to controlled group.

Main outcome variables

Quantitative variables like age will be measured as mean \pm Standard deviation SD. Qualitative variables like Gender, Cover screw exposure at 7th post op day and Pink esthetic score at 3rd and 6th month follow up will be measured as frequency and percentage. Chi-Square test will be applied to compare qualitative variables like Cover screw exposure on 7th post op day and Pink esthetic score after 3 and 6 months follow up between two groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230714058773N1**

Registration date: **2023-09-02, 1402/06/11**

Registration timing: **retrospective**

Last update: **2023-09-02, 1402/06/11**

Update count: **0**

Registration date

2023-09-02, 1402/06/11

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

2021-01-20, 1399/11/01

Expected recruitment end date

2021-10-19, 1400/07/27

Actual recruitment start date

2021-01-20, 1399/11/01

Actual recruitment end date

2021-10-19, 1400/07/27

Trial completion date

2021-10-20, 1400/07/28

Scientific title

Comparison of Soft Tissue Healing in Immediate Implant Placement in Fresh Extraction Socket with and without the Use of Platelet-Rich Fibrin

Public title

Comparison of Soft Tissue Healing in Immediate Implant Placement in Fresh Extraction Socket with and without the Use of Platelet-Rich Fibrin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Presence of maxillary or mandibular tooth
Tooth indicated for extraction without any active infection
Presence of adequate and harmonious gingival architecture with the surrounding dentition
Adequate bone volume bone height and width
Good oral hygiene

Exclusion criteria:

Edentulous Patients . . Patients on chemotherapy
Patients on radiotherapy
Systemic diseases such as diabetes
Habit of Smoking
Any active infection surrounding tooth indicated for extraction
Poor oral hygiene

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

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

2021-01-19, 1399/10/30

Ethics committee reference number

905/Trg-ABP1K2

Health conditions studied

1

Description of health condition studied

Implant Placement, Extraction Socket, Platelet-Rich Fibrin

ICD-10 code

Z96.5

ICD-10 code description

Presence of tooth-root and mandibular implants

Primary outcomes

1

Description

Cover screw exposure

Timepoint

0 and 7th post op day

Method of measurement

Will be measured as frequency and percentage. Chi-Square test will be applied to compare qualitative variable like Cover screw exposure on 7th post op day between two groups

2

Description

Pink esthetic score

Timepoint

3rd and 6th month after intervention

Method of measurement

Will be measured as frequency and percentage. Chi-Square test will be applied to compare qualitative variable like Pink esthetic score after 3 and 6 months follow up between two groups

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 Patients selected according to inclusion criteria i.e Minimum age 18-60 years, presence of maxillary or mandibular tooth, tooth indicated for extraction without any active infection, presence of adequate and harmonious gingival architecture with the surrounding dentition, adequate bone volume bone height and width, good oral hygiene, immediate implant placement was done after extraction with the use of

platelet rich-fibrin. Patients instructed to revisit for follow up on 7th day to evaluate Cover screw exposure. And after 3 and 6 months they checked for Pink esthetic score.

Category

Treatment - Surgery

2**Description**

Control group: 30 Patients selected according to inclusion criteria i.e Minimum age 18-60 years, presence of maxillary or mandibular tooth, tooth indicated for extraction without any active infection, presence of adequate and harmonious gingival architecture with the surrounding dentition, adequate bone volume bone height and width, good oral hygiene, immediate implant placement was done after extraction without the use of platelet rich-fibrin. Patients instructed to revisit for follow up on 7th day to evaluate Cover screw exposure. And after 3 and 6 months they checked for Pink esthetic score.

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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Rawalpindi

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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

Range road Rawalpindi

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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

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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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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