

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 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

**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**

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**Position**

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**Latest degree**

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**Email**

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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