Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 crieteria: min age 18-60 years old, presence of Maxillary and mandibular teeth without active infection, with healthy surrounding tissue Exclusion crieteria: 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 ± 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

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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

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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
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Armed forces institute of dentistry CMH Rawalpindi
Full name of responsible person
Tehmina Maryam
Position
Registrar
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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