

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The comparison of the effect of PRF and CGF on immediate implant treatment after the extraction of teeth with the periapical lesion.

Protocol summary

Study aim

The comparison of Platelet-rich plasma (PRF) and Concentrated growth factor (CGF) in the treatment of immediate implant of teeth with the periapical lesion.

Design

Clinical Trial with the control group, with parallel groups, randomized, 2-3rd phase on 27 patients. The randomization tool is the random number table.

Settings and conduct

Patients referring to the dentistry faculty of Guilan are chosen if matched with inclusion criteria; divided into 3 groups and related intervention according to the group will be performed. This study is not blinded.

Participants/Inclusion and exclusion criteria

Healthy patient in terms of systemic diseases, with remaining roots, soft tissue, and buccal bone plate in a normal distance from the CEJ, plaque index less than 25%, and teeth with periapical lesion was included in the study. Smoking, pregnancy, history of radiotherapy and chemotherapy, active infection, type 2 and 3 sockets, advanced periodontitis and marginal bone recession, blood disease and diabetes, periapical lesion larger than 7 millimeters and Bruxism lead to exclusion of the patient from the study

Intervention groups

After the extraction of the tooth with a periapical lesion, in the control group, the immediate implant is placed; in the first intervention group Platelet-rich plasma with the immediate implant, and in the second intervention group Concentrated growth factor with the immediate implant is placed.

Main outcome variables

Pain is recorded using VAS 1, 6, 24, and 48 hours post-surgery. At baseline, 1st, 3rd, and 6th-month post-surgery following indices are measure: Healing of soft tissue using EHI; Esthetic of gingiva at mid buccal, mesial, and distal of the implant as 0 to 4; Plaque index and Bleeding index as a percent. At baseline, 3rd, and 6th-month post-surgery, using a radiography healing of

the lesion and crestal bone level are measured. After 6 months, IHS is reported

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039327N4**

Registration date: **2021-02-09, 1399/11/21**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-09, 1399/11/21**

Update count: **0**

Registration date

2021-02-09, 1399/11/21

Registrant information

Name

Meysam Malekzadeh

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-19, 1399/10/30

Expected recruitment end date

2021-07-21, 1400/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of PRF and CGF on immediate implant treatment after the extraction of teeth with the periapical lesion.

Public title

The effect of PRF and CGF on immediate implant treatment after the extraction of tooth with a lesion.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy patient in terms of systemic diseases Remaining roots Soft tissue and buccal bone plate in a normal distance from the CEJ Plaque index less than 25% Teeth with peri-apical lesion

Exclusion criteria:

Smoking Pregnancy History of radiotherapy and chemotherapy Active infection Type 2 and 3 socket Advanced periodontitis and marginal bone recession Blood disease and diabetes Periapical lesion larger than 7 millimeter Bruxism

AgeFrom **20 years** old to **60 years** old**Gender**

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **27****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization is conducted using R software by statistician and patients are divided into three groups based on that. To divide participants into three groups of 9 people randomly, firstly people are given a number from 1 to 27. Then with software R version 3.4.3, they are divided into three random groups. A simple randomization method has been used.

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 Guilan University of Medical Sciences

Street address

dentistry faculty of Guilan University of Medical Science, Fuman-saravan ring road, Rasht, Guilan, Iran

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Approval date

2021-01-07, 1399/10/18

Ethics committee reference number

IR.GUMS.REC.1399.461

Health conditions studied**1****Description of health condition studied**

Loss of teeth due to extraction

ICD-10 code

K08.1

ICD-10 code description

Loss of teeth due to extraction

Primary outcomes**1****Description**

Pain

Timepoint

1 hour post-surgery, 6 hours post-surgery, 24 hours post-surgery, 48 hours post-surgery

Method of measurement

Using Visual Analog Scale (VAS) which ranges from 0 to 10. So that, 0 indicates no pain and 10 indicates severe pain.

2**Description**

The healing of soft tissue

Timepoint

Immediately after the surgery, 1 month after the surgery, 3 months after the surgery, 6 months after the surgery

Method of measurement

Using Early Healing Index (EHI) which ranges from 0 to 4. 0 means complete closure of flap without fibrin line. 1 means complete closure of flap with thin fibrin line. 2 means complete closure of flap with fibrin clot. 4 means no closure of flap with partial necrosis. and 5 means no closure of flap with complete necrosis.

3

Description

The healing of the peri-apical lesion

Timepoint

Immediately after the surgery, 3 months after the surgery, 6 months after the surgery

Method of measurement

Using radiography, the decrease in the width of the lesion is reported in percent.

4

Description

The success and survival of the implant

Timepoint

6 months after the surgery

Method of measurement

Using Implant Health scale (IHS) which ranges from 1 to 4. Score 1 means "complete health" of implant and includes no presence of pain and tenderness in function, no mobility, no secretion of exudate, and the reduction of bone height is less than 2 millimeters. Score 2 means "satisfying survival" of implant and includes no presence of pain and tenderness in function, no mobility, no secretion of exudate, and the reduction of bone height is 2-4 millimeters. Score 3 means "compromised survival" of implant and includes the possible presence of pain and tenderness in function, no mobility, possible secretion of exudate, the reduction of bone height is more than 4 millimeters or less than half of the implant's length, and probing depth is more than 7 millimeters. Score 4 means "complete failure" of implant and includes the presence of pain and tenderness in function, mobility, uncontrollable secretion of exudate, the reduction of bone height is more than half of the implant's length, and probing depth is more than 7 millimeters.

Secondary outcomes

1

Description

The esthetic of gingiva in the mid-buccal of the implant

Timepoint

Immediately after the surgery, 1 month after the surgery, 3 months after the surgery, 6 months after the surgery

Method of measurement

Using Gingival Esthetic Index in the mid buccal which evaluates the difference of implant's buccal margin with adjacent tooth margin and ranges from 0-4. 0 means no difference, 1 means difference less than 1 millimeter, 2 means difference of 1- 2 millimeters, 3 means difference of 2-3 millimeters, and 4 means difference more than 3 millimeters.

2

Description

The esthetic of gingiva in the mesial and distal of the implant

Timepoint

Immediately after the surgery, 1 month after the surgery, 3 months after the surgery, 6 months after the surgery

Method of measurement

Using Gingival Esthetic Index in the mesial and distal of the implant which evaluates the height of the interdental papilla and ranges from 0-4. 0 means no presence of the papilla, 1 means the papilla's height is less than half of the gingival embrasure, 2 means the papilla's height is more than half of the gingival embrasure, 3 means complete growth of papilla into the interproximal space and 4 means the growth of papilla is over the interproximal space

3

Description

Crestal bone level

Timepoint

Immediately after the surgery, 3 months after the surgery, 6 months after the surgery

Method of measurement

Using radiography, the distance of crestal bone from the implant is reported in millimeter.

4

Description

Plaque Index

Timepoint

Immediately after the surgery, 1 month after the surgery, 3 months after the surgery, 6 months after the surgery

Method of measurement

Using the O'Leary method. The patient is given a Fuschion tablet. The presence or absence of the stained deposits on the buccal, lingual, mesial, and distal surfaces is recorded and reported as the percent of stained surfaces to total surfaces.

5

Description

Bleeding index

Timepoint

Immediately after the surgery, 1 month after the surgery, 3 months after the surgery, 6 months after the surgery

Method of measurement

Using an O Michigan probe. The gingiva is probed in mesio-lingual, mesio-buccal, mid-buccal, mid-lingual, disto-buccal, and disto-lingual. After 30 seconds, the presence or absence of bleeding is recorded and the percent of the bleeding surfaces to total surfaces is reported.

Intervention groups

1

Description

Intervention group: After the extraction of the tooth with

a periapical lesion in the first intervention group, 20 milliliters of blood sample is taken from the patient, and using a centrifuge device, Platelet-rich plasma is prepared. Platelet-rich plasma is placed in the tooth socket. The immediate implant is placed in the region.

Category

Treatment - Drugs

2**Description**

Intervention group: After the extraction of the tooth with a periapical lesion in the second intervention group, 10 milliliter of blood sample is taken from the patient and using a centrifuge device, a concentrated growth factor is prepared. Concentrated growth factor is placed in the tooth socket. The immediate implant is placed in the region.

Category

Treatment - Drugs

3**Description**

Control group: After the extraction of the tooth with a periapical lesion, the immediate implant is placed in the region.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dental faculty of Guilan University of Medical Science

Full name of responsible person

Reza Tayefeh Davalloo

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

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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

Rasht University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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**

Rasht University of Medical Sciences

Full name of responsible person

Maryam Zohary

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Maryam Zohary

Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

If requested through an email, data will be sent.

When the data will become available and for how long

From the publication of the results

To whom data/document is available

Researchers

Under which criteria data/document could be used

If the reason for needing the data is explained through an email, the data will be sent.

From where data/document is obtainable

To the email Maryamzohary@gmail.com

What processes are involved for a request to access data/document

Will be sent immediately after receiving the email

Comments