Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The comparison of the effect of PRF and CGF on immediate implant treatment after the extraction of teeh 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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Iran (Islamic Republic of)

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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 teeh 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

Age
From **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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4188794755

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

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Sponsors / Funding sources

1

Sponsor

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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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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