Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

investigating the effect of advanced platelet-rich fibrin and rosuvastatin gel on the healing condition of extracted tooth socket

Protocol summary

Study aim
Determining effect of advanced platelet-rich fibrin and rosuvastatin gel in the healing of extracted tooth socket

Design
Controlled clinical trial, with four-arm parallel-group, single-blinded, randomized, on 36 patients

Settings and conduct
Patients referring to the dental faculty of Guilan university of medical science are chosen if they have the inclusion criteria. Patients are divided into three intervention groups and one control group based on a table of random numbers. In group A, as a spontaneously healing control group, after tooth extraction and socket washing with normal saline, suturing was performed. Groups B, C, and D also include those who receive A-PRF +, Rosuvastatin, and a mix of A-PRF + and Rosuvastatin, respectively, and then sutured Hidden X suture with 4-0 silk and needle 19. For the single-blinding of the study, the primary and secondary outcomes are evaluated by one of the project partners.

Participants/Inclusion and exclusion criteria
Patients 20 to 60 years old, with not-restorable or crowned teeth, with root fractures and extensive decay, with residual roots without apical lesions, soft tissue and buccal bone plate at a normal distance from CEJ, dental atraumatic extraction, and healthy individuals are the inclusion criteria. Smokers, pregnant and lactating women, a history of radiation therapy and chemotherapy, sensitivity to statin drugs, socket type II or III, injecting bisphosphonate, adjacent to the edentulous area are exclusion criteria.

Intervention groups
Patients are divided into 4 groups. Group A, as control group of spontaneous healing of socket, and groups B, C, and D receive A-PRF +, Rosuvastatin, and A-PRF + / Rosuvastatin, respectively.

Main outcome variables
Pain, healing of soft and hard tissue of extracted tooth socket, Bucco-lingual width, Mesio-dista, height and buccal wall thickness of extracted tooth socket, Histo-pathology evaluation

General information

Reason for update

Acronym
APRF

IRCT registration information
IRCT registration number: **IRCT20180416039327N3**
Registration date: **2020-07-27, 1399/05/06**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-27, 1399/05/06**
Update count: **0**

Registration date
2020-07-27, 1399/05/06

Registrant information

Name
Meysam Malekzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 13 3348 6416

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malekzadeh@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-18, 1399/04/28

Expected recruitment end date
2020-11-04, 1399/08/14

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

investigating the effect of advanced platelet-rich fibrin and rosuvastatin gel on the healing condition of extracted tooth socket

Public title

the effect of rosuvastatin gel on healing of extracted tooth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient with not restorable tooth or crown, a root fracture, extensive decay Residual roots without apical lesions Soft tissue and buccal bone plate at normal distance from CEJ Atraumatic tooth extraction People who are in complete health status

Exclusion criteria:

smokers Pregnant and lactating women History of radiation therapy and chemotherapy Sensitivity to statin drugs Socket Type II or III Injecting bisphosphonate Adjacent to the toothless area

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize in the relevant groups, a four Permuted block randomization method will be used. Randomization will be done by software of SAS (statistical analysis system version 9).

Blinding (investigator's opinion)

Single blinded

Blinding description

The researcher who had measured and recorded the indices were not aware of the intervention which was performed for patients to conduct single blinding.

Placebo

Not used

Assignment

Factorial

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

fouman saravan ring road, GUMS complex , dentistry university

City

rasht

Province

Guilan

Postal code

73774-41941

Approval date

2020-07-18, 1399/04/28

Ethics committee reference number

IR.GUMS.REC.1399.190

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

6, 24 and 48 hours post surgery

Method of measurement

Using VAS which is reported as 0 (No pain) to 10 (Severe pain)

2

Description

the healing of soft tissue of extracted tooth socket

Timepoint

at baseline and 10 days after the surgery

Method of measurement

Landry index is recorded from 1 to 5 based on erythema, granulation tissue, bleeding in palpation and incision line.

3

Description

the healing of hard tissue of extracted tooth socket

Timepoint

at baseline, 4 and 12 weeks after surgery

Method of measurement

Amount of bone trabecule formed in the extracted tooth socket is measured in parallel peri-apical radiography using ImageJ software

Secondary outcomes

1

Description
Bone trabeculae size
Timepoint
3 months after the surgery
Method of measurement
By histo-pathology evaluation

2

Description
Percentage of mineralized bone
Timepoint
3 months after the surgery
Method of measurement
By histo-pathology evaluation

3

Description
Percentage of Osteoidal tissue
Timepoint
3 months after the surgery
Method of measurement
By histo-pathology evaluation

4

Description
Bucco-lingual width of extracted tooth socket
Timepoint
baseline and 3 months after the surgery
Method of measurement
Using a probe this index is measured in millimeter from a reference point on the adjacent tooth.

5

Description
Mesio-distal width of extracted tooth socket
Timepoint
baseline and 3 months after the surgery
Method of measurement
Using a probe this index is measured in millimeter from a reference point on the adjacent tooth.

6

Description
Height of extracted tooth socket
Timepoint
baseline and 3 months after the surgery
Method of measurement
Using a probe this index is measured in millimeter from a reference point on the adjacent tooth.

7

Description
thickness of buccal wall of extracted tooth socket
Timepoint
baseline and 3 months after the surgery
Method of measurement
Using a Colis

Intervention groups

1

Description
Control group: spontaneous healing of extracted tooth socket that will not receive any special intervention.
Category
N/A

2

Description
Intervention group: Advanced platelet-rich fibrin in extracted tooth socket
Category
Treatment - Other

3

Description
Intervention group: Rosuvastatin gel in extracted tooth socket
Category
Treatment - Drugs

4

Description
Intervention group: Advanced platelet-rich fibrin and Rosuvastatin gel in extracted tooth socket
Category
Treatment - 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
Street address
Rasht, fuman-saravan ring road, dentistry faculty of Guilan University of Medical Science
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4188794755
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+98 13 3348 6416

Email
dental@gums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mehran Taromsari
Street address
Rasht, fuman-saravan ring road, dentistry faculty of Guilan University of Medical Science
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4188794755
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Email
dental@gums.ac.ir
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
fahimeh khaqani
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
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Person responsible for scientific inquiries

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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Resident
Latest degree
Medical doctor
Other areas of specialty/work
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4188794755
Phone
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Email

khaqanif@yahoo.com

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
Data of evaluated index (landry index, visual analog scale,use of analgesics, radiography bone trabeculae) will be released.
When the data will become available and for how long
6 months after the publication of final results
To whom data/document is available
Anyone can access the data
Under which criteria data/document could be used
In order to conduct similar research , the date will be accessible
From where data/document is obtainable
Malekzadeh@gums.ac.ir khaqanif@yahoo.com
What processes are involved for a request to access data/document
After sending an email and explaining the similar research they are performing, the data will be accessible in 4 weeks
Comments