

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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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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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

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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
fahimeh khaqani

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
Meysam Malekzadeh

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

Contact

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Email

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 data 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