Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the quality of formed bone and pain after use of platelet rich fibrin (PRF) and Simvastatin in the extracted tooth socket

Protocol summary

Study aim
Determining and comparing the effect of placing Simvastatin and platelet rich fibrin on the level of pain and the quality of bone formed in the socket of extracted teeth.

Design
A single-blind, parallel-group, randomized clinical trial on 19 patients. Randomization is done using a table of random numbers.

Settings and conduct
The selected patients need to have two teeth extracted on both sides of the jaw and are candidates for implant treatment. Silent selection is randomized to platelet-rich fibrin (PRF) or Simvastatin. The sample size of 38 people in two groups of 19 is randomly selected with a table of random numbers. The ingredients are placed in absorbable collagen (Gelfoam) and the patient does not know about the ingredients. After tooth extraction, we put PRF on one side and Simvastatin on the other side. 3 months later, for implant treatment, sampling is done and interpreted by light microscope. In the current study, the information that can distort the results of the intervention (such as the type, shape, color, smell, and method of intervention treatment) is hidden from the participant.

Participants/Inclusion and exclusion criteria
Including criteria is patients candidate for implant replacement of two similar hopeless tooth of both sides of a jaw, between age 20 to 65 years old. Excluding criteria is systemic diseases, the use of steroids, history of radiotherapy, diabetes, pregnancy, smoking, periodontal disease and allergy.

Intervention groups
The intervention group includes patients who need tooth extraction for implant treatment and who receive PRF intervention. The comparison group includes patients who need tooth extraction for implant treatment and receive Simvastatin intervention.

Main outcome variables
bone quality; felt pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171015036782N10**
Registration date: **2024-09-27, 1403/07/06**
Registration timing: **prospective**

Last update: **2024-09-27, 1403/07/06**
Update count: **0**

Registration date
2024-09-27, 1403/07/06

Registrant information

Name
farzane vaziri

Name of organization / entity
Shahid sadoughi dental university

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-10-06, 1403/07/15

Expected recruitment end date
2025-02-03, 1403/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the quality of formed bone and pain after use of platelet rich fibrin (PRF) and Simvastatin in the extracted tooth socket

Public title
Evaluation the effect of Simvastatin and platelets rich fibrin in the socket of extracted teeth.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
age between 20 to 65 years old candidate for implant insertion of both sides of a jaw two similar hopeless tooth of both sides of a jaw

Exclusion criteria:
Pregnancy Smoking Using immunosuppressive medications Uncontrolled diabetes Systemic disease History of radiotherapy Allergy Periodontal disease

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **19**
More than 1 sample in each individual
Number of samples in each individual: **2**
split mouth

Randomization (investigator's opinion)
Randomized

Randomization description
The method of randomizing the samples is done using a table of random numbers. In order to hide the random allocation, the method of using a non-transparent sealed envelope is also used. In this way, two envelopes are prepared with aluminum fibers (in order to make the contents of the envelopes unclear) and each of the random intervention methods is recorded on a card and the cards are placed inside the envelopes in order. At the start of the intervention, based on the order of the intervention, one of the letter envelopes is opened and its assigned group is revealed.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the participants will not be aware of the type of prescribed drug

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of yazd University of Medical Sciences

Street address
No.2,Second Alley, East touba Ave, Amirkabir Blvd ,Yazd

City
Yazd

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Yazd

Postal code
8916147860

Approval date
2023-07-31, 1402/05/09

Ethics committee reference number
IR.SSU.DENTISTRY.REC.1402.032

Health conditions studied

1

Description of health condition studied
Loss of teeth due to accident, extraction or local periodontal disease

ICD-10 code
K08.1

ICD-10 code description
Complete loss of teeth

Primary outcomes

1

Description
percentage of vital bone

Timepoint
3 months after tooth extraction at the time of the implant surgery, samples will be taken.

Method of measurement
light microscope

Secondary outcomes

1

Description
pain

Timepoint
1 and 7 days after the extractions, pain will be measured.

Method of measurement
Visual Analogue Scale

2

Description
non-vital bone
Timepoint
3 months after tooth extraction at the time of the implant surgery, samples will be taken.
Method of measurement
light microscope

3

Description
percentage of amorphous bone
Timepoint
3 months after tooth extraction at the time of the implant surgery, samples will be taken.
Method of measurement
light microscope

4

Description
Percentage of trabecular bone
Timepoint
3 months after tooth extraction at the time of the implant surgery, samples will be taken.
Method of measurement
light microscope

Intervention groups

1

Description
Intervention group: Platelet-rich fibrin extracted from 40 cc of the patient's own blood, topically in extracted tooth socket.The blood extracted from the patient is immediately placed in a centrifuge and after separating the platelets rich fibrin (PRF) along with absorbable collagen, placed in the dental socket.
Category
Other

2

Description
Intervention group: Simvastatin 20 mg manufactured by Tehran Chemical Company with the brand name Sivesterol 20, topically in extracted tooth socket. Simvastatin is powdered and then placed inside the socket of the extracted tooth by absorbable collagen.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Faridoddin Fani
Street address
Shahid Sadoughi Faculty of Dentistry Yazd, Emam Reza square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Alireza Danesh Kazemi
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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
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person

Faridoddin Fani

Position
Post graduation

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Person responsible for updating data

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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
Data sets used and/or analyzed during the present study are available from the corresponding author upon request.

When the data will become available and for how long
The access period starts 6 months after the results are published.

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Data sets used and/or analyzed during the present study are available from the corresponding author upon request.

From where data/document is obtainable
In order to receive data/documents, you can contact the author of this study through the e-mail address faridf2171@gmail.com.

What processes are involved for a request to access data/document
By sending an email to the responsible author and explaining about the applicant's project proposal and how to use the information, the requested information will be available to the applicant after 10 days after approval by the responsible author.

Comments