Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Histomorphometric investigation of the effect of rosuvastatin on the repair of dental socket bone

Protocol summary

Study aim
Histomorphometric investigation of rosuvastatin on dental socket bone repair

Design
A clinical trial with a control group (a parallel group where each individual will be compared to themselves), double-blinded (patients, surgeons, and evaluators), randomized phase 2-3 conducted on 14 patients. A coin toss will be used for randomization.

Settings and conduct
Patients who have referred to the Faculty of Dentistry of Islamic Azad University of Tehran for tooth extraction and implant placement with the indication of two identical removable teeth are selected and after both teeth are extracted in one session, rosuvastatin (Rosutex) with foam gel will be randomly placed in one of the sockets and Only gel foam will be placed in the other socket.Then the flap will be turned over and sutured to close the socket. At the next visit, which will be after 2 months for implant placement, samples of the tooth cavities will be taken for histological examination of bone quality.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients with two removable teeth, candidates for implants Exclusion Criteria: systemic diseases, diabetes, pregnancy, periodontitis, history of radiotherapy, use of steroids, allergic prophylaxis requirement

Intervention groups
Intervention group: Patients with two extractable teeth and candidates for implants, After tooth extraction using an elevator and forceps, the short implant procedure was performed, coupled with curettage and lavage of the socket with saline. Rosuvastatin (Ropixon 20, 20 mg, manufactured by Obidi Pharmaceutical Company) with foam gel will be placed in the socket. The flap will be turn and sutured to close the socket. Control group: The same individual in the intervention group, who will receive a placebo for their second dental socket.

Main outcome variables
percentage of living bone, percentage of necrotic bone, degree of inflammation, foreign body reaction

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250101064245N1**
Registration date: **2025-04-05, 1404/01/16**
Registration timing: **registered_while_recruiting**

Last update: **2025-04-05, 1404/01/16**
Update count: **0**

Registration date
2025-04-05, 1404/01/16

Registrant information
Name
Negar Valipour
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 11 3228 7658
Email address
valipour.dent@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-02-19, 1403/12/01
Expected recruitment end date
2025-06-22, 1404/04/01
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Histomorphometric investigation of the effect of rosuvastatin on the repair of dental socket bone

Public title

Investigating the effect of rosuvastatin on bone

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients applying for implant placement referred to the dental unit of Islamic Azad University Patients who have an indication of two matching teeth that can be extracted

Exclusion criteria:

systemic diseases diabetes pregnancy periodontitis history of radiation therapy use of steroids needing allergic prophylaxis

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **14**

More than 1 sample in each individual

Number of samples in each individual: **2**

Two identical removable teeth that require implants

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be conducted using a purposive sampling method. The selection of the socket intended to be filled with rosuvastatin will occur through random allocation. In this manner, for each patient, the cavities will be organized in accordance with the Universal numbering system. In this method, the numbering of the upper jaw third molar on the left receives the number 1, and the remaining upper jaw teeth are sequentially numbered from left to right, such that the upper jaw third molar on the right receives the number 16. For the lower jaw, the numbering continues from the right third molar, which is assigned the number 17. Subsequently, the numbering continues sequentially from right to left, with the final tooth, the lower jaw third molar on the left, receiving the number 32. Accordingly, the tooth that is assigned a smaller number is designated as A, and the other tooth is designated as B. The allocation of the intervention type to teeth A and B will be executed using a random coin toss method, facilitated by the flipping of a coin. This process will be overseen by the study's statistical consultant and will take place prior to the implementation of the interventions. The outcomes of the random allocation will be provided to the researcher preparing the gel in sealed envelopes, which will be sequentially opened during the intervention to procure the gels accordingly.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, a placebo will also be utilized. The primary drug consists of a gel that is impregnated with rosuvastatin, while the placebo comprises a gel that is devoid of rosuvastatin. patients, researchers, and the surgical dentist will remain unaware of the contents of the gels (rosuvastatin + gel or gel alone). Patients will not be informed regarding which cavity contains the drug and which cavity contains the placebo. The surgical dentist will also lack information about the two groups and will only be provided with two packages labeled A and B. For each patient, after the cavities have been systematically numbered according to the Universal numbering system, package A will be applied to the tooth with the smaller number and package B to the other tooth. Additionally, When evaluating dependent variables by the assessor, they will also have no information regarding the type of medication or placebo in the examined cavities.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran Islamic Azad University

Street address

No. 4, Neyestan 10 Alley, Pasdaran Street

City

tehran

Province

Tehran

Postal code

1946853314

Approval date

2024-11-30, 1403/09/10

Ethics committee reference number

IR.IAU.DENTAL.REC.1403.157

Health conditions studied

1

Description of health condition studied

Dental implants and repairing dental socket

ICD-10 code
Z96.5
ICD-10 code description
Presence of tooth-root and mandibular implants

Primary outcomes

1

Description
percentage of living bone
Timepoint
before the intervention and 2 months after the implant placement
Method of measurement
Nikon YS-100 optical microscope with 100 magnification and a scaled lens

2

Description
percentage of necrotic bone
Timepoint
before the intervention and 2 months after the implant placement
Method of measurement
Nikon YS-100 optical microscope with 100 magnification and a scaled lens

3

Description
degree of inflammation
Timepoint
before the intervention and 2 months after the implant placement
Method of measurement
Nikon YS-100 optical microscope with 100 magnification and a scaled lens

4

Description
foreign body reaction
Timepoint
before the intervention and 2 months after the implant placement
Method of measurement
Nikon YS-100 optical microscope with 100 magnification and a scaled lens

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention group:" In patients who have an indication for two identical extractable teeth, after extracting both teeth in one session, curettage and rinsing of the cavity with saline will be performed, and one of the sockets that will have a smaller number based on the universal numbering method will be selected. Rosuvastatin (Ropixon 20, 20 mg, manufactured by Obidi Pharmaceutical Company) will be mixed in the form of a powder mixture with gel foam powder (one 20 mg tablet) by normal saline and placed in the tooth socket. Then the flap will be turned over and sutured to close the socket opening. After 2 months, the patient will be called back and the dependent variables under study will be measured.
Category
Treatment - Drugs

2

Description
Control group: In this study, the control group will consist of the same patients as the intervention group (parallel control). Patients with two extractable teeth and candidates for implants, After tooth extraction using an elevator and forceps, the short implant procedure was performed, coupled with curettage and lavage of the socket with saline. foam gel (one 20 mg tablet in powder form) will be placed in the socket. The flap will be turn and sutured to close the socket.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dentistry Faculty of Tehran Islamic Azad University
Full name of responsible person
Dr Sare Farhadi
Street address
No. 4, Neyestan 10 Alley, Pasdaran Street
City
Tehran
Province
Tehran
Postal code
1946853314
Phone
+98 21 2256 4571
Email
dr.sfarhadi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr Arash Azizi
Street address
No. 4 - 10 Nistan Alley – Pasdaran St

City
Theran
Province
Tehran
Postal code
1946853314
Phone
+98 21 2258 0925
Email
drarashazizi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Dr Sare Farhadi
Position
Faculty member
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
No. 4, Neyestan 10 Alley, Pasdaran Street
City
Tehran
Province
Tehran
Postal code
1946853314
Phone
+98 21 2256 4571
Email
dr.sfarhadi@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr Sare Farhadi
Position
Faculty member
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
No. 4, Neyestan 10 Alley, Pasdaran Street
City
Tehran
Province
Tehran
Postal code
1946853314
Phone
+98 21 2256 4571
Email
dr.sfarhadi@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Negar Valipour
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
No. 4, Neyestan 10 Alley, Pasdaran Street
City
Tehran
Province
Tehran
Postal code
1946853314
Phone
+98 11 3228 7658
Fax
Email
valipour.dent@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available