

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of simvastatin and collagen on the healing condition of extracted tooth socket (histomorphometric evaluation).

Protocol summary

Study aim

Determining effect of simvastatin with collagen compared to collagen on the healing of extracted tooth socket

Design

Controlled clinical trial, with two-arm parallel-group, single-blinded, randomized, on 40 patients

Settings and conduct

Patients referring to the dental faculty of Shahid Sadoughi Yazd university of medical science are chosen if they have the inclusion criteria. Patients are divided into two intervention and control groups based on a table of random numbers. In group A, as a control group, after tooth extraction and socket washing with normal saline and inserting collagen, suturing was performed. Groups B include those who receive Simvastatin, 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 with not-restorable or crowned teeth, with root fractures and extensive decay, with residual roots without apical lesions, 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 are exclusion criteria.

Intervention groups

Patients are divided into 2 groups. Group A, as control group receive collagen and group B receive Simvastatin and collagen

Main outcome variables

healing of hard tissue of extracted tooth socket, Bucco-lingual width, Mesiodistal, height and buccal wall thickness of extracted tooth socket, Histo-pathology evaluation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200324046848N1**

Registration date: **2020-12-03, 1399/09/13**

Registration timing: **retrospective**

Last update: **2020-12-03, 1399/09/13**

Update count: **0**

Registration date

2020-12-03, 1399/09/13

Registrant information

Name

seyyedeh nasrin fa'al rastegar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3730 1370

Email address

nasrinrastegar26@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-23, 1397/10/02

Expected recruitment end date

2020-04-22, 1399/02/03

Actual recruitment start date

2018-12-23, 1397/10/02

Actual recruitment end date

2020-04-22, 1399/02/03

Trial completion date

2020-06-29, 1399/04/09

Scientific title

Investigating the effect of simvastatin and collagen on the healing condition of extracted tooth socket (histomorphometric evaluation).

Public title

The effect of simvastatin on healing of extracted tooth socket

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 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

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Investigator

Sample size

Target sample size: **40**

Actual sample size reached: **35**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with randomization table. Randomization is done using Random allocation software (RAS)version 2 by writing the number of groups and the sample size in the specified field and clicking on the generate random list option gives each sample a code in which The group is placed. Allocation concealment as Sequentially numbered, opaque, sealed envelopes (SNOSE); is. The sealed envelopes are given to the ward secretary and she registers the patients.

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

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Sadoughi University of Medical Sciences

Street address

Fajr Ave., Emam Reza Square., Dentistry Faculty of Shahid Sadoughi University of Medical Sciences and Health Services Yazd

City

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Province

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Postal code

8914881167

Approval date

2018-12-31, 1397/10/10

Ethics committee reference number

IR.SSU.REC.1397.120

Health conditions studied**1****Description of health condition studied**

Loss of teeth due to extractio

ICD-10 code

K08.1

ICD-10 code description

Complete loss of teeth

Primary outcomes**1****Description**

The healing of hard tissue of extracted tooth socket

Timepoint

At baseline and 8 weeks after surgery

Method of measurement

Amount of bone trabecule formed in the extracted tooth socket is measured in histologic specimen using ImageJ software

Secondary outcomes**1****Description**

Percentage of mineralized bone

Timepoint

2 months after the surgery

Method of measurement

By histo-pathology evaluation

Intervention groups**1****Description**

Intervention group: Simvastatin 10 mg and native

collagen (Bone Protect Cone,Dentegris GmbH,Germany)
in extracted tooth socket

Category

Treatment - Drugs

2**Description**

Control group: Receive native collagen cone
(BoneProtect Cone,Dentegris GmbH,Germany) in
extracted tooth socket

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Sadoughi University of Medical Sciences and
Health Services Yazd

Full name of responsible person

Nasrin Faal Rastegar

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Fajr Ave., Emam Reza Square., Dentistry Faculty of
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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Mahdie Khezri

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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

Farzane Vaziri

Position

Assistant Professor

Latest degree

Specialist

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

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Resident

Latest degree

Medical doctor

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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 of evaluated index will be released.

When the data will become available and for how long

6 months after the publication of final result

To whom data/document is available

Anyone can access the dat

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

nasrinrastegar26@gmail.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