

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Determining the effects of using 1.2% Atorvastatin gel with absorbable membrane on clinical and histological parameters in socket preservation

#### Protocol summary

2021-07-22, 1400/04/31

##### Study aim

This study aimed to assess the effect of Atorvastatin gel on clinical and histological parameters in dental socket preservation

##### Design

Randomized clinical trial with control group, parallel group and double blind, on 15 patients

##### Settings and conduct

The present clinical trial is performed on 15 patients who need to extract at least two teeth. In each patient, Atorvastatin gel with collagen membranes are used to maintain the alveolar socket on one side and collagen membranes on the other side. The patient is not aware of the type of treatment.

##### Participants/Inclusion and exclusion criteria

Patients who required extraction of two teeth

##### Intervention groups

Atorvastatin gel with resorbable collagen membrane in intervention group and resorbable collagen membrane in control group

##### Main outcome variables

Width and height of dental socket; width and thickness of gingiva before and 2 months after intervention; histology index of ossification percentage and thickness of trabeculae, 2 months after intervention

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110109005570N11**

Registration date: **2021-07-22, 1400/04/31**

Registration timing: **prospective**

Last update: **2021-07-22, 1400/04/31**

Update count: **0**

##### Registration date

##### Registrant information

###### Name

Parichehr Behfarnia

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1666 1707

###### Email address

behfarnia@dnt.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-07-23, 1400/05/01

##### Expected recruitment end date

2021-10-23, 1400/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Determining the effects of using 1.2% Atorvastatin gel with absorbable membrane on clinical and histological parameters in socket preservation

##### Public title

Effect of Atorvastatin gel on clinical and histological parameters in socket preservation

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Patient with healthy systemic condition Single-rooted or

double-rooted teeth Presence of sound buccal and lingual plates after tooth extraction Presence of a minimum of 10 mm vertical bone height without invading the adjacent critical structures,

**Exclusion criteria:**

Allergy to collagen membrane Severe untreated periodontitis Acute infection or pus at the extraction site

**Age**

From **30 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **15**

More than 1 sample in each individual

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

15 patients who required extraction of two teeth

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In each patient, one dental socket is selected as the case and the other socket as the control. Randomization method for selecting the socket in each patient is done by the sealed envelope.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The participant is not able to identify the type of treatment performed. The person performing the histological examination is not aware of the type of treatment.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Hezar Jarib- Isfahan University of Medical Sciences

**City**

Esfahan

**Province**

Isfahan

**Postal code**

814673461

**Approval date**

2020-05-31, 1399/03/11

**Ethics committee reference number**

IR.MUI.MED.REC.1398.107

**Health conditions studied**

**1**

**Description of health condition studied**

socket preservation

**ICD-10 code**

K08.40

**ICD-10 code description**

Partial loss of teeth, unspecified cause

**Primary outcomes**

**1**

**Description**

Length of socket

**Timepoint**

Before the intervention and 2 months after the intervention

**Method of measurement**

Periodontal probe

**2**

**Description**

Width of socket

**Timepoint**

Before the intervention and 2 months after the intervention

**Method of measurement**

Periodontal probe

**3**

**Description**

Width of keratinized gingiva

**Timepoint**

Before the intervention and 2 months after the intervention

**Method of measurement**

Periodontal probe

**4**

**Description**

Thickness of gingiva

**Timepoint**

Before the intervention and 2 months after the intervention

**Method of measurement**

Periodontal probe

**5**

**Description**

Percent of ossification of alveolar socket

**Timepoint**

2 months after the intervention

**Method of measurement**

Histological evaluation

**6**

**Description**

Thickness of new trabecula

**Timepoint**

2 months after the intervention

**Method of measurement**

Histological evaluation

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: extraction of tooth and placing atorvastatin gel in socket and covering it with claprotect membranes made by Bottis company and then suturing on it

**Category**

Treatment - Other

**2**

**Description**

Control group: extraction of tooth and covering socket by claprotect membranes made by Bottis company and then suturing on it

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Dental school, Medical University of Isfahan

**Full name of responsible person**

Parichehr Behfarnia

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Nakisa Torabinia

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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**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Parichehr Behfarnia

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

**Contact**

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Shiraz University of Medical Sciences

**Full name of responsible person**

seyedh Negin Hosseini

**Position**

assistant professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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Seyedeh Negin Hosseini

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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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**

All data can be shared after unidentifying individuals

**When the data will become available and for how long**

Start the access period after printing the results

**To whom data/document is available**

for all researcher

**Under which criteria data/document could be used**

For a comparative study

**From where data/document is obtainable**

Dr. Negin Hosseini, assistant professor of dental school,  
Shiraz University of Medical Sciences

**What processes are involved for a request to access data/document**

Request via email to the corresponded and will be send  
within 3 months after review

**Comments**