

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### Clinical evaluation of the effect of allograft alone, or in combination with simvastatin gel in the treatment of mandibular class II furcation defects in human

#### Protocol summary

##### Summary

Objective: Evaluation of effects of simvastatin gel in combination with allograft on improvement of clinical parameters and bone fill in furcation involvement grade II mandibular molars compared to allograft alone. This randomized clinical trial is double blind and accomplished on ten patients with chronic periodontitis. Inclusion criteria: a pair of first or second mandibular teeth bilaterally with furcation involvement class II that have at least 3 mm horizontal penetration of probe in furca. At least 2 mm keratinized gingiva. Exclusion criteria: smoking; history of systemic disease; pregnant or breast feeding females; history of antibiotic consumption within 2 months; history of periodontal treatment within 6 months; history of hypersensitivity or treatment with statin; aggressive periodontitis; mobility grade 3; pulp pathology of teeth and poor oral hygiene. CBCT are taken and clinical parameters with probe in furca are measured. Following clinical parameters are measured at baseline and 6 months post-surgery: plaque index, bleeding index, recession, probing depth, and clinical attachment level, horizontal and vertical depth. After local anesthesia, full thickness incision with maintenance of keratinized gingiva was done. Then, reflect the flap and debridement. Measurement of horizontal and vertical bone loss is repeated and recorded. In test group, allograft bone chips combined with patient blood and simvastatin gel are put in furcation defect. Then, the defect is covered with allograft membrane. After early healing of soft tissue, surgery is done on the control side. Allograft bone chips with blood and placebo gel are put in the defect. Similar to test group, other steps of operation were done. During monthly visits, plaque and gingival index are recorded due to maintain optimal patient's hygiene. In after 6 month visit, clinical and radiographic parameters are reevaluated and recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016112631116N1**

Registration date: **2017-01-07, 1395/10/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-01-07, 1395/10/18

##### Registrant information

##### Name

Zahra Nasiri

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3727 4820

##### Email address

za\_nasiri@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research and Technology center, Shiraz University of Medical Sciences

##### Expected recruitment start date

2015-11-22, 1394/09/01

##### Expected recruitment end date

2016-01-21, 1394/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Clinical evaluation of the effect of allograft alone, or in combination with simvastatin gel in the treatment of mandibular class II furcation defects in human

**Public title**

Effect of simvastatin gel on periodontitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: 1- presence at least 1 pair of first or second molar of mandible bilaterally accompanied with fraction involvement class 2 with less or equal 3 mm horizontal penetration of probe. 2- presence at least 2 mm keratinized gingiva around each tooth. Exclusion criteria: 1- smoking. 2- history of systemic disease. 3- pregnant or breast feeders. 4- history of antibiotic consumption within 2 months. 5- hx of periodontal treatment within 6 months. 6- hx of hypersensitivity to statins. 7- pt with statin treatments. 8- aggressive periodontitis. 9- tooth mobility grade 3. 10- pulp-pathology and incomplete RCT or PA lesion. 11- poor oral hygiene.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 10

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Research and Technology Center

**Street address**

Zand Blv.

**City**

Shiraz

**Postal code****Approval date**

2015-11-01, 1394/08/10

**Ethics committee reference number**

IR.SUMS.REC.1394.131

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

Furcation involvement class 2 mandible molars (periodontitis)

**ICD-10 code**

K05.6

**ICD-10 code description**

Periodontal disease, unspecified

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

Clinical Attachment Level

**Timepoint**

preoperative, during and 6 months post surgery

**Method of measurement**

probe and CBCT

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

Recession

**Timepoint**

before Surgery- during Surgery- 6 month after

**Method of measurement**

Periodontal probe

**2****Description**

Bone Fill

**Timepoint**

before Surgery- during Surgery- 6 month after

**Method of measurement**

Periodontal probe and CBCT

**3****Description**

Probing pocket depth

**Timepoint**

before Surgery- during Surgery- 6 month after

**Method of measurement**

Periodontal probe and CBCT

**4****Description**

Horizontal penetration in the Furca  
**Timepoint**  
before Surgery- during Surgery- 6 month after  
**Method of measurement**  
Periodontal probe and CBCT

## 5

**Description**  
Bleeding Index  
**Timepoint**  
before Surgery- during Surgery- 6 month after  
**Method of measurement**  
Periodontal probe

## 6

**Description**  
Plaque Index  
**Timepoint**  
before Surgery- during Surgery- 6 month after  
**Method of measurement**  
Periodontal probe

## Intervention groups

### 1

**Description**  
Intervention group: allograft and membrane and simvastatin gel are used. After local anesthesia and incision in the target area, flap were reflected, debridement was performed, then allograft with simvastatin gel put in the defect, membrane adapted on the defect and suture the flap  
**Category**  
Treatment - Surgery

### 2

**Description**  
Control group: allograft with placebo gel. After local anesthesia and incision in the target area, flap were reflected, debridement was performed, then allograft put in the defect, membrane adapted on the defect and suture the flap  
**Category**  
Treatment - Surgery

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Perio department, Dentistry school,  
**Full name of responsible person**  
Dr. Farin Kiany  
**Street address**  
Shiraz Dental School  
**City**  
Shiraz

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Dr Basir Hashemi  
**Street address**  
Zand Blv. Central Office of SUMS  
**City**  
Shiraz  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shiraz University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
*empty*  
**Domestic or foreign origin**  
*empty*  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

**Contact**  
**Name of organization / entity**  
Shiraz Dentistry School  
**Full name of responsible person**  
Dr. Farin Kiany Yazdy  
**Position**  
Associate professor/ supervisor  
**Other areas of specialty/work**  
**Street address**  
Perio department, Dentistry School, Ghasrdasht  
**City**  
Shiraz  
**Postal code**  
**Phone**  
+98 71 3628 9919  
**Fax**  
**Email**  
farinkiany@yahoo.com  
**Web page address**

## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
Shiraz Dentistry School  
**Full name of responsible person**  
Dr. Farin Kiany Yazdy

**Position**

Associate professor

**Other areas of specialty/work****Street address**

Perio department, Dentistry School, Ghasrdasht

**City**

Shiraz

**Postal code****Phone**

+98 71 3628 9919

**Fax****Email**

farinkiany@yahoo.com

**Web page address**

Ghasrdasht Street- Shiraz Dental School

**City**

Shiraz

**Postal code****Phone****Fax****Email**

farinkiany@yahoo.com

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*

**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz Dentistry School

**Full name of responsible person**

Dr. Farin Kiany

**Position**

Associate professor

**Other areas of specialty/work****Street address**