Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the effects of subgingival injection of Simvastatin on prevention of the tooth relapse after orthodontic movements

Protocol summary

Summary

Objectives: The purpose of this study is to evaluate the effect of Simvastatin on tooth relapse after orthodontic tooth movements and its effect on the gingival index besides Clinical Attachment Loss. Design: This is a single blinded, non-randomized clinical trial that is carried out parallel. Setting and conduct: After attached all spaces with constant orthodontic instruments, gingival index besides Clinical Attachment Loss measured first for all the patients. Participants including major eligibility criteria: Female patients with 4 to 6 mm space between front teeth of upper or lower gingival are entered to study. Besides patients under systemic therapy with simvastatin group medicines and sever periodontitis patients are excluded from this study. Intervention: The patients will be divided into two equal groups. For the first group, normal saline injection as placebo carry out in the sixth front teeth depth pocket with 1.2 mg for each inter proximal section, two weeks after bleaching and for the second group, simvastatin injection carry out in the sixth front teeth depth pocket with 1.2 mg for each inter proximal section, two weeks after bleaching. Main outcome and measures variables: The relapse will be measured through calculating the created space by photography and Smile Analyzer into two groups. Also gingival index besides Clinical Attachment Loss will be calculated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013041813054N1**
Registration date: **2013-11-04, 1392/08/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-11-04, 1392/08/13

Registrant information

Name
Parasto Namdar
Name of organization / entity
Mashhad University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Research chancellor of Mashhad University of Medical Sciences

Expected recruitment start date

2013-04-30, 1392/02/10

Expected recruitment end date

2014-05-10, 1393/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effects of subgingival injection of Simvastatin on prevention of the tooth relapse after orthodontic movements

Public title

Simvastatin effect on orthodontic relapse

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Female patients with 20 to 45 years old, with 4 to 6 mm space between front teeth of upper or lower gingival, controlled chronic periodontitis with Clinical Attachment Loss of 4 to 6 mm and without known allergy to simvastatin group medicines. Big tongue was not the cause of space. Exclusion criteria: Patients under systemic therapy with simvastatin group medicines, pregnant or breath feeding patients, sever periodontitis patients, smoker or alcoholic patients, patients with diabetes or immunosuppressive diseases.

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Central Building of Mashad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City
Mashhad

Postal code
91375-345

Approval date
2011-11-01, 1390/08/10

Ethics committee reference number
900303

Health conditions studied

1

Description of health condition studied
orthodontic relapse

ICD-10 code
Z46.4

ICD-10 code description
Fitting and adjustment of orthodontic device

Primary outcomes

1

Description
Gingival index

Timepoint
Before the study and eight weeks after injection in control and intervention group

Method of measurement
According to bleeding index

2

Description
Clinical Attachment Loss

Timepoint
Before the study and eight weeks after injection in control and intervention group

Method of measurement
By Probe

Secondary outcomes

empty

Intervention groups

1

Description
For control group: normal saline injection (1 .2 mg) in the sixth front teeth depth pocket, two weeks after bleaching

Category
Treatment - Drugs

2

Description
For intervention group: simvastatin injection in the sixth front teeth depth pocket with 1.2 mg for each inter proximal section, two weeks after bleaching

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mashhad dentistry school

Full name of responsible person
Dr Arezo Jahanbin

Street address
Mashhad dentistry school, Azadi Square

City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
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City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Mashhad 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

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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