

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 51 1883 0787

Email address

namdarp881@mums.ac.ir

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 breast feeding patients, severe 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 Mashhad 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

Street address

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

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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

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Parasto Namdar

Position

orthodontic resident

Other areas of specialty/work

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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