

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Local clinical effect of simvastatin tablets on pain after maxillary premolar tooth extraction in patients recommended for orthodontic treatment

Protocol summary

Study aim

Clinical Effect of Simvastatin Tablets on Reducing Pain After Extracted Maxillary Maxillary Teeth in Patients Referring to Orthodontic Treatments

Design

Clinical trial with control group, with parallel groups, one blind, randomized

Settings and conduct

This research was carried out in the surgery department of Mazandaran Dental School, and the whole process of removing the teeth, inserting the simvastatin drug into silence and suturing, was done by one person (designer).

Participants/Inclusion and exclusion criteria

Patients with systemic problems, or certain drugs, as well as addicts and smokers were excluded from the study and only healthy patients were examined. The criteria for entering the study include the age range of 18-35 years, and the orthodontic order to remove any of the two first premolars for future orthodontic treatment. Also, the teeth should not have periapical radiographic changes and caries, and they should also be removed by local anesthetic and non-surgical forceps and anesthesia.

Intervention groups

To assign each pair to the control or intervention group based on the first or second time, using the random numbers table, 10 people were assigned to the intervention group

Main outcome variables

The findings of this study indicate that in general, the pain level in the local consumption group of simvastatin was significantly higher than the control group at all times than 6 hours after tooth extraction, which is statistically significant have been. There is also no relationship between sex and age with the amount of pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190701044070N1**

Registration date: **2019-07-06, 1398/04/15**

Registration timing: **retrospective**

Last update: **2019-07-06, 1398/04/15**

Update count: **0**

Registration date

2019-07-06, 1398/04/15

Registrant information

Name

sanaz akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4426 7456

Email address

sanazkbr@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-28, 1397/08/06

Expected recruitment end date

2019-03-13, 1397/12/22

Actual recruitment start date

2018-10-28, 1397/08/06

Actual recruitment end date

2019-03-13, 1397/12/22

Trial completion date

2019-03-13, 1397/12/22

Scientific title

Local clinical effect of simvastatin tablets on pain after maxillary premolar tooth extraction in patients recommended for orthodontic treatment

Public title

The effect of simvastatin on reducing tooth pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The orthodontic order to extract of each 2 maxillary premolars for future orthodontic treatment

Exclusion criteria:**Age**

From **18 years** old to **35 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant

Sample size

Target sample size: **10**

More than 1 sample in each individual

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

First maxillary premolar teeth on the left and the right

Actual sample size reached: **10**

More than 1 sample in each individual

Actual sample size in each individual: **2**

First maxillary premolar teeth on the left and the right

Randomization (investigator's opinion)

Randomized

Randomization description

To assign each pair to the control group or the intervention based on the first or second time, using the random numbers table, 10 people will be assigned to the intervention group and 10 will be assigned to the control group. Patients with systemic problems, or certain drugs, as well as addicts and smokers will be removed from the study group, and only healthy patients will be examined. The criteria for entering the study can be from the age of 35 to 18 years, and the orthodontic order for the removal of each of the first two premolars in the right and left upper jaw. Also, the teeth should not have periapical radiographic changes and can also be removed by forceps and local anesthetics. The pain according to the patient's own opinion, based on the subjective criteria and according to the Visual Analog Scale (VAS), will be available at the intervals before, 30 minutes later, 6 hours, 12 hours and 24 hours after surgery. . In addition, the patient is urged to visit the department 7 days a day to examine and pull sutures.

Blinding (investigator's opinion)

Single blinded

Blinding description

This clinical trial is parallel, randomized, and blind clinical trials. In the intervention group, the gelatin sponge coated with simvastatin (10 mg, combined with saline) (Poursina, Tehran, Iran) was placed in silence and then sutured with suture wrap 3 to 3 vikril. In the control

group, just after washing, only gelatin sponge is placed and the silent just sutures.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name****Secondary trial Id****Registration date**

empty

2**Registry name****Secondary trial Id****Registration date**

empty

3**Registry name****Secondary trial Id****Registration date**

empty

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

Ethics Committee of Mazandaran University of Medical Sciences

Street address

medical university of mazandaran, Vali asr Ave., sari, Iran

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2019-04-08, 1398/01/19

Ethics committee reference number

IR.MAZUMS..REC13983394

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

tooth pain

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

The amount of pain

Timepoint

Before, 30 minutes later, 6 hours, 12 hours and 24 hours after surgery

Method of measurement

The VAS is a 10-cm linear scale that is graded from zero to ten and is zero in the no-pain sense and ten most severe pain. After considering the line, the patient determines the amount of pain on the line, and then the pain is calculated based on millimeters from the origin of zero.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first premolar was the one used with simvastatin

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry Sari

Full name of responsible person

Dr. Reza Mofidian

Street address

Mazandaran University of Medical Sciences and Health Services, Beginning of Valiasr highway, Sari, Mazandaran

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sari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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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

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Reza Mofidian

Position

University teacher

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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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

Clinical Effect of Simvastatin Tablets on the Post-Injury of Premolar Maxillary Pain in Patients Referring to Orthodontic Treatments

When the data will become available and for how long

It's ready

To whom data/document is available

University - Supervisor - Student

Under which criteria data/document could be used

To reduce tooth pain and under any circumstances

From where data/document is obtainable

Student

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

University permit - Propeller - Research - Conclusion - Thesis

Comments