

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effects of adjunctive use of 2% atorvastatin dentifrice plus vitamin C in treatment of chronic periodontitis

Protocol summary

Clinical variables are Probing depth, clinical attachment loss, , bleeding on probing and Modified gingival index

Study aim

To determine the effectiveness of using atorvastatin 2% toothpaste with vitamin C as a supplement in the non surgical periodontal treatment of chronic periodontitis patients

Design

In this double-blind study, 72 patients with moderate to severe chronic periodontitis referring to periodontics department of Shahid Sadoughi Dental School of Yazd will be selected and after coding will be randomly divided into four intervention and control groups.

Settings and conduct

Initially, the levels of Modified Gingival Index (MGI), Bleeding on probing (BOP), Clinical Attachment Loss (CAL) and Probing Depth (PD) will be recorded for patients and after non-surgical periodontal treatment and receiving toothpaste and oral vitamin C in intervention groups for 4 weeks, patients will be recalled and the levels of PD, CAL, MGI and BOP will be re-evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria are the age between 30 to 60 years and the moderate to severe chronic periodontitis. Exclusion criteria include pregnancy, breast feeding, smoking, using immunosuppressive medications and NSAIDs and antibiotics and vitamin supplements and mouthwash, Autoimmune diseases, uncontrolled diabetes and Hyperlipidemia disease.

Intervention groups

non-surgical periodontal treatment will be done for all the patients and The control group will use 0.2% fluoride toothpaste as an adjunct treatment, Group II: as an adjunct treatment, use toothpaste containing 0.2% fluoride and atorvastatin 2%. Group III: as an adjunct treatment, using 0.2% fluoride toothpaste along with chewable tablets 250 mg of vitamin C. Group IV: as an adjunct treatment use toothpaste containing 0.2% fluoride and atorvastatin 2% with chewable tablets 250 mg of vitamin C.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171015036782N5**

Registration date: **2018-09-26, 1397/07/04**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-26, 1397/07/04**

Update count: **0**

Registration date

2018-09-26, 1397/07/04

Registrant information

Name

farzane vaziri

Name of organization / entity

Shahid sadoughi dental university

Country

Iran (Islamic Republic of)

Phone

+98 35 3620 4764

Email address

f.vaziri@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-02-09, 1397/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effects of adjunctive use of 2% atorvastatin dentifrice plus vitamin C in treatment of chronic periodontitis

Public title
Effects of adjunctive use of 2% atorvastatin dentifrice plus vitamin C in treatment of teeth supporting tissues disease.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
age between 30 to 60 years old chronic moderate to severe periodontitis
Exclusion criteria:
Pregnancy Breast feeding Smoking Using immunosuppressive medications Using NSAIDs Using antibiotics over the past 3 months Using a vitamin supplement or mouthwash Having an autoimmune disease Uncontrolled diabetes Hyperlipidemia disease Special diet

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into four groups (control and intervention groups) using a random-number table

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the participants and the investigator will not be aware of the type of prescribed drug

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of yazd University of Medical Sciences

Street address

No.2,Second Alley, East touba Ave, Amirkabir Blvd ,Yazd

City

Yazd

Province

Yazd

Postal code

8916147860

Approval date

2018-07-31, 1397/05/09

Ethics committee reference number

IR.SSU.REC.1397.061

Health conditions studied

1

Description of health condition studied

moderate to severe chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

Primary outcomes

1

Description

Probing depth

Timepoint

Beggining of study and 1 month later

Method of measurement

Williams probe

2

Description

Clinical Attachment Loss

Timepoint

Beggining of study and 1 month later

Method of measurement

Using the Williams probe

3

Description

Modified Gingival Index

Timepoint

Beggining of study and 1 month later

Method of measurement

by observation of the amount of inflammation in the mouth and then calibrate it

4

Description

Bleeding on probing

Timepoint

Beginning of study and 1 month later

Method of measurement

by observation of Bleeding on probing in the mouth and measuring its percentage

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: non-surgical periodontal treatment and daily administration of 0.2% fluoride toothpaste for 4 weeks

Category

Placebo

2**Description**

Intervention group: non-surgical periodontal treatment and daily prescription of toothpaste that contains atorvastatin 2% and 0.2% fluoride for 4 weeks

Category

Treatment - Drugs

3**Description**

Intervention group: non-surgical periodontal treatment and daily prescription of 0.2% fluoride toothpaste and Chewable tablets of vitamin C with dose of 250 mg for 4 weeks

Category

Treatment - Drugs

4**Description**

Intervention group: non-surgical periodontal treatment and daily prescription of toothpaste that contains atorvastatin 2% and 0.2% fluoride plus Chewable tablets of vitamin C with dose of 250 mg for 4 weeks

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Amirhosein Vatandoust

Street address

Shahid Sadoughi Faculty of Dentistry Yazd, Emam Reza square

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Yazd

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8915839985

Phone

+98 35 3621 2623

Email

amirhosein.vatandoust@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Alireza Danesh Kazemi

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Shahid Sadoughi Faculty of Dentistry Yazd, Emam Reza Square

City

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Postal code

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Email

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

Amirhosein Vatandoust

Position

Post graduation

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Amirhosein Vatandoust

Position

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

Yazd University of Medical Sciences

Full name of responsible person

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The whole data is shared

When the data will become available and for how long

Six months after the publication of the article

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Email, Call

From where data/document is obtainable

amirhosein vatandoust, 09121713074,

amirhosein.vatandoust@yahoo.com

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

After sending the Email, the data will be transmitted

Comments