

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

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

#### Protocol summary

##### 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

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

#### 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**  
Beginning of study and 1 month later

**Method of measurement**  
Williams probe

### 2

**Description**  
Clinical Attachment Loss

**Timepoint**  
Beginning of study and 1 month later

**Method of measurement**  
Using the Williams probe

### 3

**Description**  
Modified Gingival Index

**Timepoint**  
Beginning 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

**City**

Yazd

**Province**

Yazd

**Postal code**

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

**Street address**

Shahid Sadoughi Faculty of Dentistry Yazd, Emam Reza Square

**City**

Yazd

**Province**

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**Postal code**

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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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**Latest degree**

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**Person responsible for updating data****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**

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**Email**

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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**