

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Atorvastatin Local Gel Application and Placebo on Periodontal Clinical Indices in Patient with Chronic Periodontitis

Protocol summary

Study aim

Evaluation of the Atorvastatin Local Gel Application Effectiveness on Periodontal Clinical Indices in Patient with Chronic Periodontitis

Design

Clinical trial with control group, 2 arm parallel group, Double-blinded, randomized, phase 2 on 40 pockets in 20 patients, randomization was done with random numbers table.

Settings and conduct

Place: Specialized department of the Faculty of Dentistry, Isfahan University of Medical Sciences. Conduct: Assignment of each of the two quadrants from the mouth of each patient by split mouth protocol into two areas one receiving treatment and the other being control. Blinding: Patient and therapist are both blind to the intervention because Atrovastatin and placebo gel have A and B labels and aren't identifiable.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Systemic health; age of 30-60 years old; have mild to moderate chronic periodontitis; presence of at least 20 teeth; presence of at least 2 pockets with 4-7 mm of probing depth and CAL of equal to or greater than 3 mm. Non-inclusion criteria: Smoking; pregnancy; use of cholesterol-lowering drugs or antibiotic medications in the past 1 month; presence of orthodontic appliances.

Intervention groups

Intervention group: Atorvastatin; Atorvastatin gel will be applied for intended pocket by a blunt tip insulin syringe. Control group: Placebo; placebo gel will be applied for intended pocket by a blunt tip insulin syringe.

Main outcome variables

Pocket depth; clinical attachment level; sulcular bleeding index.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150210021029N4**

Registration date: **2021-03-02, 1399/12/12**

Registration timing: **retrospective**

Last update: **2021-03-02, 1399/12/12**

Update count: **0**

Registration date

2021-03-02, 1399/12/12

Registrant information

Name

Sima Kiani

Name of organization / entity

Department of Periodontology, dental school, Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 2842

Email address

simakiani@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Atorvastatin Local Gel Application and

Placebo on Periodontal Clinical Indices in Patient with Chronic Periodontitis		quadrant gel A and for the second, gel B will be applied and vice versa if it is tails.	
Public title	Evaluation of effect of Atorvastatin gel on treatment of periodontal inflammatory disease	Blinding (investigator's opinion)	Double blinded
Purpose	Treatment	Blinding description	Participant: They don't know which side of their mouth is taking medication or placebo. Care provider and investigator: In terms of packaging, color and consistency, the pharmaceutical gel and placebo are completely similar and are named with the letters A and B for each bottle. Data analyser: All data is converted to numbers as code, without defining code in the file given to the analyzer.
Inclusion/Exclusion criteria	Inclusion criteria: Having mild to moderate chronic periodontitis (bone crest distance from CEJ>2, Clinical Attachment Loss≥3) Having at least 20 teeth Not having bridge, crown or orthodontic braces in gel application area Having at least 2 pockets with 4-7mm of probing depth and CAL of equal to or greater than 3mm Having general health Exclusion criteria: Having systemic diseases Pregnancy and lactation Receiving periodontal treatment and/or usage of antibiotics during 1 month before treatment Presence of aggressive periodontitis and systemic conditions affecting the periodontal condition Malnutrition and impaired immune status Smoking Using statins or allergy to them Presence of symptoms of corona virus disease or similar symptoms Using drugs that affect oral tissues Use of antibiotics Use of cholesterol-lowering drugs such as statins	Placebo	Used
Age	From 30 years old to 60 years old	Assignment	Parallel
Gender	Both	Other design features	
Phase	3	Secondary Ids	empty
Groups that have been masked	- Participant - Care provider - Investigator - Data analyser	Ethics committees	
Sample size	Target sample size: 20 More than 1 sample in each individual Number of samples in each individual: 2 Each person has one side of the mouth as a Control and the other side as an example of treatment	<u>1</u>	
Randomization (investigator's opinion)	Randomized	Ethics committee	
Randomization description	Participants selection in the study will be performed by simple randomization method, individually and with random number table tools. In this way, a number will be written in front of the name of each person from the list of clients, then a table will be designed based on the sample size of the study, and we'll blindly touch a number of table numbers. The selected numbers will be included in the study if they are eligible after the examination. The intervention will be performed in a parallel design, and the choice of individuals' quadrant for Intervention or Control will be randomly performed with coin instruments. In such a way that for both quadrants which their numbers are accidentally put in the list, we drop a coin and if it's head for the first	Name of ethics committee	Ethics Committee of Isfahan University of Medical Sciences
		Street address	Isfahan University of Medical Sciences, Hezarjerib street, Isfahan
		City	Isfahan
		Province	Isfahan
		Postal code	7346181746
		Approval date	2020-11-01, 1399/08/11
		Ethics committee reference number	IR.MUI.RESEARCH.REC.1399.462
		Health conditions studied	
		<u>1</u>	
		Description of health condition studied	chronic periodontitis
		ICD-10 code	K05.3
		ICD-10 code description	Chronic periodontitis
		Primary outcomes	
		<u>1</u>	
		Description	Pocket Depth

Timepoint

At baseline (before the intervention) and at 6 weeks and 3 months after gel application

Method of measurement

Williams Periodontal Probe (Hu-Friedy®, USA)

2

Description

Clinical Attachment Level

Timepoint

At baseline (before the intervention) and at 6 weeks and 3 months after gel application

Method of measurement

Williams Periodontal Probe (Hu-Friedy®, USA)

3

Description

Modified Sulcular Bleeding Index

Timepoint

At baseline (before the intervention) and at 6 weeks and 3 months after gel application

Method of measurement

Williams Periodontal Probe (Hu-Friedy®, USA)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After the primary sampling, scaling and oral hygiene education, by split-mouth protocol for each patient in one quadrant (which was selected by randomization by coin instrument) Atorvastatin gel is injected and after 6 weeks and 3 months the secondary sampling will be performed.

Category

Treatment - Drugs

2

Description

Control group: After the primary sampling, scaling and oral hygiene education, by split-mouth protocol for each patient in one quadrant (which was selected by randomization by coin instrument) placebo gel is injected and after 6 weeks and 3 months the secondary sampling will be performed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry; Isfahan University of Medical

Sciences

Full name of responsible person

Sima Kiani

Street address

Faculty of Dentistry, Isfahan University of Medical Sciences, Hezarjerib Ave, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3669 2588

Email

research@dnt.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Nakisa Torabinia

Street address

Vice chancellor for Research; Isfahan Dental School; Isfahan University of Medical Sciences, Hezarjerib street

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3792 5512

Email

research@dnt.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Sima Kiani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Dentistry School, Isfahan University of Medical Sciences, Hezarjerib street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3792 5542

Email

Simakiani@dnt.mui.ac.ir

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

Esfahan University of Medical Sciences

Full name of responsible person

Sima Kiani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Phone

+98 31 3792 5542

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

Esfahan University of Medical Sciences

Full name of responsible person

Sima Kiani

Position

Assistant professor

Latest degree

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Dentistry

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Province

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Email

Simakiani@dnt.mui.ac.ir

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

Data related to Personal information and Indicators examined in the study. All Data can be shared after making people unidentifiable.

When the data will become available and for how long

Up to One year after publication of the Article

To whom data/document is available

Researchers working in Academic and Scientific Institutions

Under which criteria data/document could be used

In addition to mentioning the name and academic affiliation, the applicant must have signed a letter stating that he or she does not intend to publish or use any of our study data in person

From where data/document is obtainable

Applicants can contact this E-mail: skiani.dnt@gmail.com

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

The Project Manager will provide the requested Documents via E-mail no later than One week after receiving the E-mail from the Applicant

Comments