

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation of the effect of local Atorvastatin gel application on levels of gingival crevicular fluid cytokines IL-17 and TGF- β in patients with chronic periodontitis and comparison with placebo

Protocol summary

Study aim

Evaluation of the effect of Atrovastatine gel application on levels of GCF cytokines IL-17 and TGF- β of patients with chronic periodontitis

Design

A clinical trial with a control group, 2 arm parallel-group, Double-blind, randomized, phase 2 on 40 pockets in 20 patients, randomization was centralized with randomized number table

Settings and conduct

Place: specialized department of the faculty of dentistry, University of Isfahan. Conduct: assignment of each of the two quadrants from the mouth of each patient by splitting mouth protocol into two areas one receiving treatment and the other, would be as control. Blinding: patient and therapist are both blinded because Atorvastatin and placebo gel has A and B labels.

Participants/Inclusion and exclusion criteria

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

Intervention groups

Intervention group: Atorvastatin gel will be applied to the intended pocket by a blunt tip insulin syringe. Control group: placebo gel will be applied to the intended pocket by a blunt tip insulin syringe.

Main outcome variables

IL-17 and TGF- β levels.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150210021029N5**

Registration date: **2021-06-09, 1400/03/19**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-09, 1400/03/19**

Update count: **0**

Registration date

2021-06-09, 1400/03/19

Registrant information

Name

Sima Kiani

Name of organization / entity

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

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of local Atorvastatin gel application on levels of gingival crevicular fluid cytokines IL-17 and TGF- β in patients with chronic periodontitis and comparison with placebo

Public title

Effect of atorvastatin gel on GCF cytokines of patients with chronic periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having mild to moderate chronic periodontitis (bone crest distance from CEJ>2, Clinical Attachment Loss $\geq$ 3)
Having at least 20 teeth Not having a bridge, crown, or orthodontic braces in the gel application area
Having at least 2 pockets with 4-7mm of probing depth and CAL of equal to or greater than 3mm

Exclusion criteria:

Having systemic diseases
Nonconformity of the prescribed diet
Pregnancy and lactation
Showing coronavirus disease symptoms or similar symptoms
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
Using drugs that affect oral tissues
Use of antibiotics
Use of cholesterol-lowering drugs such as statins

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

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

Randomization (investigator's opinion)

Randomized

Randomization description

Participant selection in the study will be performed by simple randomization method, individually and with random numbers table tool. 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 a quadrant in each

individual for intervention or as control will be randomly performed with coin instruments. In such a way that we drop a coin and for the first quadrant, the head means gel A and for the second, gel B will be applied and vice versa if it is tail.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant: participants will not know which side of their mouth will take medication or a 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: Data is evaluated as a number without specifying the position of the gel and the Placebo

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan university of medical sciences, Hezarjerib Ave, Isfahan

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Postal code

7346181746

Approval date

2021-02-21, 1399/12/03

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.729

Health conditions studied

1

Description of health condition studied

chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

Primary outcomes

1

Description

Mean IL-17 level

Timepoint

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

Method of measurement

ELISA IL-17 Human Kit

2

Description

Mean TGF- β level

Timepoint

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

Method of measurement

ELISA TGF- β Human Kit

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 will be selected by randomization by coin) Atorvastatin gel will be injected once into the depth of sulcus of the considered tooth and after 6 weeks and 3 months the secondary sampling will be performed.

Category

Treatment - Drugs

2

Description

Intervention group: After the primary sampling, scaling and oral hygiene education, by split-mouth protocol for each patient in one quadrant (which will be selected by randomization by coin) Placebo gel will be injected once into the depth of sulcus of the considered tooth and after 6 weeks and 3 months the secondary sampling will be performed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan University of Medical Sciences, School of Dentistry

Full name of responsible person

Sima Kiani

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Nakisa Torabinia

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Research vice chancellor, Isfahan Dental School, Isfahan University of Medical Sciences, Hezarjerib Ave, Isfahan

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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

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

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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

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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

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 People have not been identified

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