Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative evaluation of locally delivered 1.2% Rosuvastatin gel, 1% Metformin gel and placebo as an adjunct to scaling and root planing in the treatment of moderate to severe chronic periodontitis patients

Protocol summary

Study aim

The aim of the present study is to evaluate and compare the clinical efficacy of locally delivered 1.2% Rosuvastatin and 1% Metformin gel as an adjunct to scaling and root planing in the treatment of moderate to severe chronic periodontitis patients.

Design

Clinical trial with control group, parallel group design of 30 patients, single blinded, phase 2.

Settings and conduct

In the periodontology department of Ahvaz University of Medical Sciences, 30 patients with moderate to severe chronic periodontitis were selected by available sampling method and were randomly divided into 3 treatment groups during the process: 1)SRP plus 1.2% RSV gel 2)SRP plus 1% MF gel 3)SRP plus placebo gel. Clinical parameters including Pocket Probing Depth, Clinical Attachment Level, Modified Sulcus Bleeding Index and Plaque Index were recorded at baseline before SRP and after 3 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Moderate to severe chronic periodontitis patients with no history of any kind of periodontal or antibiotic therapy in the last 6 month. Exclusion criteria: Patients with any disabling systemic disease or a systemic disease that affects the periodontium, systemic statin or metformin therapy, Diabetic patients, known or suspected allergy to statins or metformin, Immunocompromised patients, Pregnant or lactating women, Individuals who use any forms of tobacco and alcoholics.

Intervention groups

1)Scaling and root planing plus 1.2% Resuvastatin gel 2)Scaling and root planing plus 1% Metformin gel 3)Scaling and root planing plus placebo gel.

Main outcome variables

Pocket Probing Depth ; Clinical Attachment Level ; Modified Sulcus Bleeding Index ; Plaque Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191024045232N1**
Registration date: **2020-11-04, 1399/08/14**
Registration timing: **retrospective**

Last update: **2020-11-04, 1399/08/14**
Update count: **0**

Registration date

2020-11-04, 1399/08/14

Registrant information

Name

Saminalsadat Ayoubi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3338 2491

Email address

ayoubi.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

2019-10-01, 1398/07/09

Actual recruitment end date

2019-12-14, 1398/09/23

Trial completion date
2020-04-08, 1399/01/20

Scientific title
Comparative evaluation of locally delivered 1.2% Rosuvastatin gel, 1% Metformin gel and placebo as an adjunct to scaling and root planing in the treatment of moderate to severe chronic periodontitis patients

Public title
Comparative evaluation of locally delivered 1.2% Rosuvastatin gel, 1% Metformin gel and placebo as an adjunct to scaling and root planing in the treatment of moderate to severe chronic periodontitis patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Moderate to severe chronic periodontitis patients with probing depth≥5mm and clinical attachment loss≥3mm. Patients with no history of any kind of periodontal or antibiotic therapy in the last 6 months.

Exclusion criteria:
Individuals with any disabling systemic disease or a systemic disease that affects the periodontium. Patients on systemic statin or metformin therapy. Diabetic patients Patients with known or suspected allergy to statins or metformin. Immunocompromised patients. Pregnant or lactating women. Individuals who use any forms of tobacco and alcoholics.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
In this single blind study, participants did not know which of the two control or experimental groups they belonged to. But the principle investigator knew who was in what group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Scineces

Street address
No. 112,West 13th st.,Kianpars

City
Ahvaz

Province
Khouzestan

Postal code
6155863861

Approval date
2019-09-21, 1398/06/30

Ethics committee reference number
IR.AJUMS.REC.1398.449

Health conditions studied

1

Description of health condition studied
Periodontitis

ICD-10 code
K05.3

ICD-10 code description
Chronic periodontitis

Primary outcomes

1

Description
Pocket Probing Depth

Timepoint
Before scaling and root planing (baseline) and after 3 months

Method of measurement
UNC 15 color-coded periodontal probe

2

Description
Clinical Attachment Level

Timepoint
Before scaling and root planing (baseline) and after 3 months

Method of measurement
UNC 15 color-coded periodontal probe

3

Description
Modified Sulcus Bleeding Index

Timepoint
Before scaling and root planing (baseline) and after 3 months

Method of measurement

Scoring system of Mombelli

4

Description
Plaque Index
Timepoint
Before scaling and root planing (baseline) and after 3 months
Method of measurement
Scoring system of Silness and Loe

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the first intervention group, treatment has been done by scaling and root planing with only single injection of 0.1ml Resuvastatin gel [consisting of 1.2% Resuvastatin (high purity that has been provided by Abidi Pharmaceutical Company), 4% hydroxypropyl methylcellulose, 5% glycerin And up to 100% water], immediately after scaling the whole mouth using a syringe with blunt tip into the pocket that has the highest probing depth and clinical attachment loss with BoP (one area per patient). In the second intervention group, treatment has been done by scaling and root planing with only single injection of 0.1ml Metformin gel [consisting of 1% Metformin (high purity that has been provided by Abidi Pharmaceutical Company), 4% hydroxypropyl methylcellulose, 5% glycerin and up to 100% water], immediately after scaling the whole mouth using a syringe with blunt tip into the pocket that has the highest probing depth and clinical attachment loss with BoP (one area per patient). Patients in both groups are given the same oral hygiene instruction and are advised not to chew any hard or sticky foods and not to brush near the treated site or to use any interdental aids for a duration of one week. No anti-inflammatory or anti-plaque mouthwash and no antibiotics are prescribed after treatment. In the recall visits, any adverse effects are recorded and any supragingival plaque or calculus is removed.
Category
Treatment - Drugs

2

Description
Control group: In the control group, treatment has been done by scaling and root planing with only single injection of 0.1ml placebo gel, immediately after scaling the whole mouth using a syringe with blunt tip into the pocket that has the highest probing depth and clinical attachment loss with BoP (one area per patient). Patients are given oral hygiene instruction similar to the intervention groups and are advised not to chew any hard or sticky foods and not to brush near the treated site or to use any interdental aids for a duration of one week. No anti-inflammatory or anti-plaque mouthwash and no antibiotics are prescribed after treatment. In the recall visits, any adverse effects are recorded and any supragingival plaque or calculus is removed.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of periodontics, Faculty of dentistry, Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Saminalsadat Ayoubi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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

Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Saminalsadat Ayoubi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Associate professor

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Specialist

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Person responsible for updating data

Contact

Name of organization / entity
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Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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http://behsan.ajums.ac.ir/general/homePage.action

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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