

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of the effect of non-surgical periodontal treatment on biochemical indicators of metabolic syndrome: A Controlled Randomized Clinical Trial

Protocol summary

Study aim

The main objective of the project: To determine the effect of non-surgical periodontal treatment on biochemical indicators of metabolic syndrome

Design

The study is an unblinded two arm parallel group randomized, controlled clinical trial. This study will be conducted on 54 patients. Patients will be divided into two intervention and control groups. The sealed envelope website will be used for randomization.

Settings and conduct

Patients with stage 1 and 2 periodontitis who were referred to Gorgan Dental School during the study will be included in the study if they are eligible and will be randomly assigned to two intervention and control groups using a randomized block design. Blinding is not possible in this study due to the nature of non-surgical periodontal treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The metabolic syndrome of the individuals participating in this study was confirmed by an endocrinologist, and these patients also had chronic periodontitis stages 1 and 2 and were referred to the Faculty of Dentistry for treatment. Exclusion criteria: Having any disease affecting periodontal tissue except metabolic syndrome, having undergone periodontal treatments in the past 6 months.

Intervention groups

Intervention group: The treatment for this group will be health education and non-surgical periodontal treatment. This treatment will include plaque removal, plaque control, supra- and sub-gingival scaling, root planing all of which is done using a piezoelectric device. Control group: in the control group, health education will be used, which will be in the form of teaching the correct frequency and method of brushing teeth and the correct use of dental floss.

Main outcome variables

Primary outcomes: fasting blood sugar, triglycerides, cholesterol, blood pressure, abdominal obesity, and HDL.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231123060153N3**

Registration date: **2025-05-20, 1404/02/30**

Registration timing: **registered_while_recruiting**

Last update: **2025-05-20, 1404/02/30**

Update count: **0**

Registration date

2025-05-20, 1404/02/30

Registrant information

Name

Amir reza Ahmadiania

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-29, 1404/02/09

Expected recruitment end date

2025-10-31, 1404/08/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of non-surgical periodontal treatment on biochemical indicators of metabolic syndrome: A Controlled Randomized Clinical Trial

Public title

Evaluation of the effect of non-surgical periodontal treatment on biochemical indicators of metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with 1st or 2nd Stage of periodontitis Ages between 35 to 60 Definitive metabolic syndrome diagnosis in both groups Having at least 20 teeth Consent for participation

Exclusion criteria:

Having any kind of disease that could effect periodontal tissue other than matabolic syndrome like: Papillon-lefevre, Treacher Collins, Aggressive periodontitis, AIDS and End Stage Renal Disease Taking any medication that could effect periodontal tissue such as: Nifedipine and Phenytoin Using orthodontic treatments or fixed long span prostheses or removable prostheses Taking Anti-biotics, Immunosuppressive drugs or Non-steroidal anti-inflammatory drugs for one week in last six month Using periodontal treatment in last six month

AgeFrom **35 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **54****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients would be randomized into two groups by Randomized block method with blocks of size 4. The website sealed envelope with <https://sealedenvelope.com> address will be used to prepare a random list of patients and this work is prepared by a project associate who has no role in treating patients. To keep the random list hidden until the beginning of patients treatment, opaque and identical envelopes will be used. Each envelope will have the patient number written on it and the treatment the patient should receive. Given that in this study, the intervention will include scaling of the patients' teeth, there is no possibility of blinding the patient and the treating physician to the treatment the patient will receive, and the patient and the treating dentist are aware of the type of treatment the patients will receive.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Golestan University of Medical Sciences

Street address

Falsafi Higher Education Complex, The beginning of Shasat Kola Road, Gorgan

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Postal code

4934174515

Approval date

2025-04-20, 1404/01/31

Ethics committee reference number

IR.GOUMS.REC.1404.023

Health conditions studied**1****Description of health condition studied**

Metabolic syndrome

ICD-10 code

E88.81

ICD-10 code description

Metabolic syndrome

2**Description of health condition studied**

Non-surgical periodontal treatment

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

Chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

Primary outcomes

1

Description

Fasting blood sugar factor value in blood test

Timepoint

Measuring the level of fasting blood sugar before the intervention and 3 and 6 months after the end of intervention.

Method of measurement

Glucometer

2

Description

Triglycerides factor value in blood test

Timepoint

Measuring the level of triglyceride before the intervention and 3 and 6 months after the end of intervention.

Method of measurement

Triglyceride Oxidase method

3

Description

Cholesterol factor value in blood test

Timepoint

Measuring the level of cholesterol before the intervention and 3 and 6 months after the end of intervention.

Method of measurement

Cholesterol Oxidase method

4

Description

HDL factor value in blood test

Timepoint

Measuring the level of HDL before the intervention and 3 and 6 months after the end of intervention.

Method of measurement

Enzymatic method

5

Description

Abdominal obesity in centimeters

Timepoint

Measuring the level of abdominal obesity before the intervention and 3 and 6 months after the end of intervention.

Method of measurement

Tape measure

6

Description

Blood pressure

Timepoint

Measuring Blood pressure before the intervention and 3 and 6 months after the end of intervention.

Method of measurement

Mercury sphygmomanometer

Secondary outcomes

1

Description

Gingival recession

Timepoint

Measuring the amount of gingival recession before the intervention and 3 and 6 months after the end of the intervention

Method of measurement

Williams periodontal probe

2

Description

Clinical Attachment Loss

Timepoint

Measurement of clinical attachment loss before intervention and 3 and 6 months after the end of intervention.

Method of measurement

Williams periodontal probe

3

Description

Pocket probing depth

Timepoint

Measurement of pocket probe depth before intervention and 3 and 6 months after the end of intervention

Method of measurement

Williams periodontal probe

4

Description

Plaque index

Timepoint

Measurement of plaque index before intervention and 3 and 6 months after the end of intervention.

Method of measurement

Silness & Loe index

5

Description

Bleeding on probing

Timepoint

Measurement of bleeding on probing before the intervention and 3 and 6 months after the end of the intervention

Method of measurement

Williams periodontal probe

Intervention groups

1

Description

Intervention group: The intervention group treatment is built on oral health education and non-surgical periodontal therapy. The oral health education content consists of brushing techniques and frequency and flossing, which will be demonstrated to all patients in a one-on-one oral health instruction (OHI) session in dental school by a certified instructor who is the dentistry student who is in charge of the research. In the second step, treatment which is non-surgical periodontal therapy with a Woodpecker model: UDSL piezoelectric device will be delivered to the intervention group in a single session with no time limit. The treatment will contain plaque removal as a result of supra- and sub-gingival scaling, using the device mentioned prior in the text, Plaque control, root planing using a periodontal curette, and chemical agents such as Chlorhexidine mouthwash with 0.2% concentration as an adjunct. After that, a monthly plaque control program will be executed by the operator on phone calls. Patients will be clinically examined in 3 and 6 months afterwards and clinical periodontal parameters, fasting blood sugar, blood lipids, abdominal obesity and blood pressure will be assessed and compared to pre-treatment parameters.

Category

Treatment - Other

2

Description

Control group: In the control group, only oral health education will be used. The content of health education, including: the correct number and method of brushing and flossing, will be presented orally and individually to all patients in the control group at the beginning of the study in the dental school by the dental student implementing the project. Then, both the measurement of factors related to periodontal conditions and the measurement of metabolic syndrome factors will be performed by the dental student when the patient visits the dental school. After that, the monthly plaque control program is also followed up by the operator over the phone. Control group will be examined 3 months and 6 months later, and their clinical periodontal parameters, fasting blood sugar, blood lipids, abdominal obesity, and blood pressure will be examined and compared with before treatment.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentistry faculty of Golestan University of Medical Sciences

Full name of responsible person

Amirreza Ahmadiania

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Amir reza Ahmadiania

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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

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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