Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Ahmadinia
Name of organization / entity
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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
Age
From **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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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 educations content consists 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 which 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

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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

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 Ahmadinia

Position

Associate professor

Latest degree
Specialist
Other areas of specialty/work
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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