

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation of effect of nonsurgical periodontal therapy on hemoglobin A1c and c1 reactive protein value in type 2 diabetes mellitus pateints.

Protocol summary

Study aim

The aim of this study is to evaluate the effect of nonsurgical periodontal therapy on serum hemoglobin A1c and c1 reactive protein levels in type 2 diabetes mellitus.

Design

clinical trial with control group, with a parallel group design of 42 patients, not blinded, randomised

Settings and conduct

Diabetic patients of Razi and besat Specialty Clinics in rasht will be chosen if they satisfy inclusion criteria. At baseline of study, all patients receive HbA1C and CRP tests in the Razi laboratory, and in the first session, periodontal indices will be measured for all patients using the Williams periodontal probe. After 3 months, all patients will be rechecked.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with chronic periodontitis who have not received any periodontal or antimicrobial treatment in the past 6 months and no change in diabetic drug regimen in the past 3 months, diabetes diagnosed by a physician for approximately 6 months. exclusion criteria: chronic pulmonary disease, malignancies, heart disease, transplanted patients, history of infection and trauma, alcoholic and smoker patients, pregnant patients, patients with severe periodontitis.

Intervention groups

Patients are divided into two groups. In intervention group scaling and root planning are performed for patients by an ultrasonic device with slim head in a one hour session . supra gingival and sub gingival calculus is removed. In control group scaling and root planing are not performed. tooth brushing with modified bass technique (twice daily), using dental floss (once a day) and chlorhexidine 0.12% twice a day are Prescribed for all patients. after the study ends, Scaling and root planing will be performed for control group.

Main outcome variables

Clinical attachment loss, plaque index, gingival index, pocket depth, gingival bleeding index, c1 reactive protein and Hba1c

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190721044287N1**

Registration date: **2019-12-21, 1398/09/30**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-21, 1398/09/30**

Update count: **0**

Registration date

2019-12-21, 1398/09/30

Registrant information

Name

mohamad moshtaghi moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3348 6416

Email address

dr.moshtaghi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of effect of nonsurgical periodontal therapy on hemoglobin A1c and c1 reactive protein value in type 2 diabetes mellitus pateints.

Public title
Effect of non surgical periodontal therapy in treatment of diabetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with chronic periodontitis who have not received any periodontal treatment in the past 6 months
Periodontal patients who have not received any antimicrobial treatment in the past 3 months
Patients with at least 14 teeth in mouth and pocket depth ≥ 5 mm in at least 4 areas and clinical attachment loss ≥ 3 mm in at least 4 areas
Diabetes diagnosed by a physician for about 6 months
Patients unchanged in their diabetic drug regimen for the past 3 months
Exclusion criteria:
Patients with advanced diabetic problems (macrovascular and microvascular)
Chronic pulmonary disease
Kidney and liver disease
Malignancies
Heart disease (coronary artery disease)
Transplanted patients
History of infection and trauma
Alcoholic and Smoker
Patients Pregnant people
Patients with severe periodontitis

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 42

Randomization (investigator's opinion)
Randomized

Randomization description
The research units were divided into two groups of intervention and control, using six-dimensional permutation blocks. First, possible blocks are listed (AAABBB, ABABAB, BABABA, BBABAA and) and each block is assigned a number. Then, using a random number table, a number is chosen. The subjects are assigned to the intervention and control groups based on the block corresponding to the chosen number. This will continue until the sample size is complete.

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 Guilan University of Medical Sciences

Street address

Dental Faculty, GUMS Complex, Fuman_Saravan Ring Road,

City

Rasht

Province

Guilan

Postal code

4188794755

Approval date

2019-09-07, 1398/06/16

Ethics committee reference number

ir.gums.rec.1398.307

Health conditions studied

1

Description of health condition studied

moderate chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

2

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Hb A1c

Timepoint

At baseline and 3 months later.

Method of measurement

Sebia apparatus for measuring Hba1c using electrophoresis capillary kit.

2

Description

C1 Reactive Protein

Timepoint

At baseline and 3 month later

Method of measurement

Hitachi912 apparatus for measuring c1 reactive protein using bionik kit

3

Description

Clinical attachment loss index

Timepoint

At baseline and 3 months later

Method of measurement

Using William's periodontal probe

4

Description

Gingival index

Timepoint

At baseline and 3 month later

Method of measurement

Using Leo & Sillness gingival inflammation index

5

Description

Pocket depth index

Timepoint

At baseline and 3 month later

Method of measurement

Using William's periodontal probe

6

Description

Gingival bleeding index

Timepoint

At baseline and 3 month later

Method of measurement

Using William's periodontal probe

7

Description

plaque index

Timepoint

At baseline and 3 month later

Method of measurement

Using disclosing agent by O'leary Index method

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group scaling and root planing are performed for patients by an ultrasonic device with slim head in a one hour session . supra gingival and sub gingival calculus is removed. presence of calculus is checked by an explorer. If needed, hand instrument is used for sites which are out of access. Patients are prescribed tooth brushing with modified bass technique (twice daily), using dental floss (once a day) and chlorhexidine 0.12% twice a day.

Category

Treatment - Devices

2

Description

In control group scaling and root planing are not performed. Patients are prescribed tooth brushing with modified bass technique (twice daily), using dental floss (once a day) and chlorhexidine 0.12% twice a day. after the study ends, Scaling and root planing will be performed for control group.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Specialty Clinic

Full name of responsible person

Dr Heydar Ali Baloo

Street address

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2

Recruitment center

Name of recruitment center

Besat Specialty Clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr Shadman Nemati
Street address
In front of 17shahrivar Hospital, Siadati Ave., Namju Ave.
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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

Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Rashed Ghorbandoust
Position
Student
Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Student
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Other areas of specialty/work
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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

All data relative to measured index are shared after unidentifying patients.

When the data will become available and for how long

6 months or 1 year after the publication of final results

To whom data/document is available

Anyone can access the data

Under which criteria data/document could be used

In order to design and perform similar research or as a base for more development studys

From where data/document is obtainable

Rashed Ghorbandoust: rashed.ghd@gmail.com Dr

Mohammad Moshtaghi moghadam:

Dr.moshtaghi@gums.ac.ir

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

After sending an email and explaining about the study, they will receive the data in a month.

Comments