Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 indicies 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

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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 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. 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
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2

Recruitment center
Name of recruitment center
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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
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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
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Full name of responsible person
Rashed Ghorbandoust
Position
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Latest degree
A Level or less
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Person responsible for updating data

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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