Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the effect of nonsurgical treatment of periodontitis on serum level of IL23 ,35 in periodontitis patients with diabetes type II in comparison with the nondiabetic group: a randomized clinical trial

Protocol summary

Study aim

The aim of this study is to determine the effect of non-surgical periodontal treatment on serum levels of IL23 and IL35 in patients with periodontitis and type 2 diabetes compared to non-diabetic patients.

Design

Clinical trial with control group, parallel groups, double blind, non randomized, sample size of 30, including two groups

Settings and conduct

Thirty individuals with periodontitis with or without type 2 diabetes who have had their diabetes for at least one year have been referred to Toba Clinic and Imam Khomeini Hospital in Sari. Patients are randomly assigned into two groups of 15 intervention and control groups: 1. Patients with diabetes and periodontitis. 2. Peridonitis

Participants/Inclusion and exclusion criteria

People with type 2 diabetes and periodontitis older than 18 years old who have a withdrawal criterion. Exit criteria: Patients with advanced renal liver and heart disease and patients treated with drugs that increase insulin resistance and increase blood glucose. Contains prednisolone, cyclosporine, and ... Patients who have taken antibiotics over the past three months. Or undergo periodontal treatment. People with fewer than 14 teeth. Pregnant women, smokers and hemorrhagic diseases, and diabetic patients with uncontrolled blood glucose (8.5 <HBA1C) who need to interfere with increasing their oral doses

Intervention groups

Group One: 15 Patients with Type 2 Diabetes and Periodontitis and Group Two: 15 patients with periodontitis but without diabetes who have criteria for entry into the study are subject to scaling and root planing.

Main outcome variables

IL23 IL35

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171108037325N2**
Registration date: **2018-02-20, 1396/12/01**
Registration timing: **prospective**

Last update: **2018-02-20, 1396/12/01**
Update count: **0**

Registration date

2018-02-20, 1396/12/01

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 816 4722

Email address

maboodi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-24, 1396/12/05

Expected recruitment end date

2018-04-04, 1397/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of nonsurgical treatment of periodontitis on serum level of IL23 ,35 in periodontitis patients with diabetes type II in comparison with the nondiabetic group: a randomized clinical trial

Public title
The effect of scaling and root planning treatment on serum level of IL 23 and IL35 in patients with periodontitis and type 2 diabetes mellitus

Purpose
Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:
patient with type 2 diabetes mellitus and periodontitis

Exclusion criteria:
Patients with advanced renal liver and heart failure Patients treated with drugs that increase insulin resistance and increase blood glucose include prednisolone, cyclosporine, and others. Patients who have been taking antibiotics for the last three months or have recieved periodontal treatment Patients with fewer than 14 teeth Pregnant patients Smokers Hemorrhagic diseases Patients with uncontrolled diabetes mellitus (8.5 <HBA1C) who need to increase their dose of oral medication

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The outcome assessor, methodologist and statistical adviser are not aware of the grouping of patients

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mazandaran university of Medical Sciences

Street address
Mazandaran university of Medical Sciences, beginning of Valiasr highway,Three way of Joybar,Imam square,Sari

City
Sari

Province
Mazandaran

Postal code
4816895475

Approval date
2017-08-11, 1396/05/20

Ethics committee reference number
IR.MAZUMS.REC.96.520

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

2

Description of health condition studied
chronic periodontitis

ICD-10 code
K05.3

ICD-10 code description
Chronic periodontitis

Primary outcomes

1

Description
IL23

Timepoint
before intervention/3 months after intervention

Method of measurement
Unit Pg / ml, using Eliza Reader

2

Description
IL35

Timepoint
before intervention/3 months after intervention

Method of measurement
Unit Pg / ml, using Eliza Reader

Secondary outcomes

1

Description
probing depth
Timepoint
befor intervention / 3 months after intervention
Method of measurement
mm unit / periodontal probe

2

Description
clinical attachment loss
Timepoint
before intervention / 3 months after intervention
Method of measurement
mm unit / periodontal probe

3

Description
HBA1c
Timepoint
before intervention/3 months after intervention
Method of measurement
No unit / by spectrophotometer

4

Description
bleeding on probing
Timepoint
before intervention / 3 months after intervention
Method of measurement
no unit/using periodontal probe

5

Description
gingival index
Timepoint
before intervention / 3 months after intervention
Method of measurement
score/by obsevation

6

Description
plaque index
Timepoint
before intervention / 3 months after intervention
Method of measurement
score/by observation

7

Description
Erythrocyte Sedimentation Rate
Timepoint
before intervention / 3 months after intervention
Method of measurement
no unit/sedimentation tube

8

Description
C-Reactive Protein(CRP)
Timepoint
before intervention / 3 months after intervention
Method of measurement
Units / By Nephlometric Method

Intervention groups

1

Description
scaling and root planning
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Touba complex
Full name of responsible person
Dr.Avideh Maboodi
Street address
Sari faculty of dentistry,next to Touba complex,Khazar blvd
City
Sari
Province
Mazandaran
Postal code
4816895475
Phone
+98 11 3326 3345
Fax
+98 11 3340 5474
Email
avideh48188@yahoo.com

2

Recruitment center
Name of recruitment center
Imam Khomeini hospital
Full name of responsible person
Dr.Adeleh Bahar
Street address
Razi st.
City
Sari
Province
Mazandaran
Postal code
48166-33131
Phone
+98 11 3336 1700

Fax

Email
doctor_bahar2000@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Dr.Majid Saeedi

Street address
Faculty of Pharmacy,km 20 of Khazar Rd, Peiambare azam educating complex

City
Sari

Province
Mazandaran

Postal code
48175-861

Phone
+98 11 3354 3082

Email
majsaeedi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Sari university of medical science

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
Mazandaran University of Medical Sciences

Full name of responsible person
Dr.Avideh Maboudi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Sari Facultu of dentistry,next to Touba complex,Khazar blvd

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+98 11 3340 5474

Email
maboodi@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Dr.Adeleh Bahar

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Medical Education

Street address
Touba complex,Khazar blvd

City
Sari

Province
Mazandaran

Postal code
4816895475

Phone
+98 11 2226 1700

Email
doctor_bahar2000@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Aida Eghbalian Nouzanizadeh

Position
dental student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

Street address
Sari faculty of dentistry,next to Touba complex, Khazar blvd

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Sari

Province
Mazandaran

Postal code
4816895475

Phone

+98 11 3326 3345

Email

eghbalian73@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

at the end of the work,we just use information for data analysis

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available