

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

IL23 IL35

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. Periodontitis

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

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 science

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 received 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

before 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 observation

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 Nephelometric 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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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
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Person responsible for updating data

Contact

Name of organization / entity
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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,
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Province
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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