Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of non-surgical periodontal therapy plus Doxycycline on HbA1c in patients with type 2 diabetes mellitus (DM).

Protocol summary

Summary

"Aim":The purpose of this study is to investigate the effect of non surgical periodontal therapy on glycemic control in type 2 diabetes mellitus (type 2 DM) patients who have periodontitis. "Materials and methods":A total of 24 type 2 DM patients with periodontitis will be selected for the study, and randomly divided into two equal groups, Plaque index (PI), bleeding on probing (BOP), probing depth (PD) and clinical attachment levels (CAL) were recorded. "Group 1": (12 patients) was treated with oral hygiene instruction, scaling and root planing, and doxycycline (100 mg/day for 15 days)." Group 2": (12 patients) has the same treatment but with placebo, After 12 weeks their periodontal condition and Fasting blood sugar (FBS), glycated hemoglobin (HbA1c) level, will be reevaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014082417587N7**
Registration date: **2014-12-29, 1393/10/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-12-29, 1393/10/08

Registrant information

Name

Amirhossein Farahmand

Name of organization / entity

Dental Branch Islamic Azad University of Tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 2284 9604

Email address

perio-implant@hotmail.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-09-11, 1393/06/20

Expected recruitment end date

2015-09-11, 1394/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of non-surgical periodontal therapy plus Doxycycline on HbA1c in patients with type 2 diabetes mellitus (DM).

Public title

A randomized double-blind placebo-controlled, clinical trial on the effect of non-surgical periodontal therapy plus doxycycline on HbA1c in patients with type 2 diabetes mellitus (DM).

Purpose

Treatment

Inclusion/Exclusion criteria

"Inclusion criteria": patients with diabetes mellitus type II (at least 3 months before diagnosis, and A fasting blood sugar level of more than 125 mg/dl) and has periodontal disease is a chronic moderate (has a clinical attachment level of 3-4 mm) peritonitis, minimum of 16 natural teeth, and no periodontal treatment in the prior 6 months, had an glycated α hemoglobin (HbA1c) value between 7- 9 percent at screening, had reported no changes in diabetes medications within the last 3

months, were in the care of a physician for their diabetes. "Exclusion criteria": pregnancy or lactation, history of allergy to drugs used in the study; smoking; diabetes related emergency within 30 days ago; use of nonsteroidal anti-inflammatory drugs; or taking low dose daily aspirin (75-325 mg); use of immunosuppressive medications; antibiotic use; dialysis; risk of bleeding complications; the type of disease periodontal (Aggressive); a history of periodontal treatment in the previous 6 months; orthodontic treatment; using the removal prostheses; extensive dental caries; dental abscesses or infections.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
In this study, the patients were randomly (Balanced Block Randomization) equal divided into two groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Dental Branch, Islamic Azad University of Tehran

Street address
No 4, 10th Neyestan, Pasdaran Ave, Tehran, Iran

City
Tehran

Postal code
19585/175

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
515

Health conditions studied

1

Description of health condition studied
periodontitis

ICD-10 code
K05.3

ICD-10 code description
Periodontitis

Primary outcomes

1

Description
Periodontal pocket

Timepoint
15 days

Method of measurement
Periodontal probe

Secondary outcomes

1

Description
glycated hemoglobin (HbA1c)

Timepoint
3 months

Method of measurement
Blood test

Intervention groups

1

Description
"Intervention group": Doxycycline 100 mg was manufactured by Razak Pharmaceutical Laboratory,Tehran- Iran .

Category
Treatment - Drugs

2

Description
"Control group":Placebo of was prepared in the same manner but without the active drug in it (Made by the Faculty of Pharmaceutical Sciences, Islamic Azad University of Tehran)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental Branch Islamic Azad University of Tehran

Full name of responsible person
Amirhossein Farahmand

Street address

No4, 10th Neyestan, Pasdarn Ave, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research Council of Dental Branch Islamic Azad University of Tehran

Full name of responsible person

Amirhossein Farahmand

Street address

No 4, 10th Neyestan Alley, Pasdaran Ave, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of Research Council of Dental Branch Islamic Azad University of Tehran

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Dental Branch Islamic Azad University of Tehran

Full name of responsible person

Amirhossein Farahmand

Position

Periodontologist, Implantologist

Other areas of specialty/work

Street address

No4, 10th Neyestan Alley, Pasdaran Ave, Tehran, Iran

City

Tehran

Postal code

19585/175

Phone

+98 21 2284 9604

Fax

Email

perio-implant@hotmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Dental Branch Islamic Azad University of Tehran

Full name of responsible person

Amirhossein Farahmand

Position

Periodontologist, Implantologist

Other areas of specialty/work

Street address

No4, 10th Neyestan Alley, Pasdaran Ave, Tehran, Iran

City

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Dental Branch Islamic Azad University of Tehran

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Amirhossein Farahmand

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty