Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of non-surgical periodontal therapy with adjunctive topical doxycycline gel 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 plus subgingivally doxycycline gel 3% 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 gel for 15 days; " and Group 2": (12 patients) has the same treatment but with placebo gel, 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: **IRCT2015010517587N8**
Registration date: **2015-02-10, 1393/11/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-02-10, 1393/11/21

Registrant information

Name
Amirhossein Farahmand

Name of organization / entity
Dental Branch Islamic Azad University of Tehran

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Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2015-01-10, 1393/10/20

Expected recruitment end date

2016-02-18, 1394/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of non-surgical periodontal therapy with adjunctive topical doxycycline gel on HbA1c in patients with type 2 diabetes mellitus(DM).

Public title

A randomized , placebo controlled trial The effect of non-surgical periodontal therapy with adjunctive topical doxycycline gel 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
From **10 years** old

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
2014-10-28, 1393/08/06

Ethics committee reference number
560

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(3 percent) gel was manufactured by shahin khapour harmaceutical Laboratory,Tehran- Iran .

Category
Treatment - Drugs

2

Description
"Control group":Placebo gel of was prepared in the same manner but without the active drug in it (Made by the shahin khakpour of Pharmaceutical Laboratory,Tehran-Iran .

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

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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