

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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  $\alpha$  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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Dental Branch Islamic Azad University of Tehran

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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*