Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of non-surgical periodontal therapy plus azithromycin 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 azithromycin gel 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 azithromycin gel (2.5 percent for 15 days)." 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: **IRCT2015010517587N9**
Registration date: **2015-02-18, 1393/11/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-02-18, 1393/11/29

Registrant information

Name
Amirhossein Farahmand
Name of organization / entity
Dental Branch Islamic Azad University of Tehran
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2014-11-21, 1393/08/30

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

A randomized double-blind placebo-controlled, clinical trial the effect of non-surgical periodontal therapy plus subgingivally azithromycin 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
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
2014-11-17, 1393/08/26
Ethics committee reference number
559

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": Azithromycin 2.5 mg gel was manufactured by khakpour 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 khakpour Pharmaceutical,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

Street address

No 4, 10th Neyestan, Pasdaran 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

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Other areas of specialty/work

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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