

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Effects of local application of tetracycline gel with SRP on HbA1c & lipid profile in type2 diabetic patients

Protocol summary

Summary

Objectives: Effects of periodontal treatment in improvement of glycemic status of diabetic patients has been proven, so present study is designed to evaluate effect of mechanical and chemical periodontal treatment on glycemic status of diabetic patients. Design: Interventional randomized clinical trial. Setting and conduct: 30 diabetic patient which have inclusion criteria are selected and randomly divided to 15 patients in case group and 15 patients in control group. Case group receive conventional periodontal therapy and antibiotic therapy and control group receive only conventional periodontal therapy. Participants including major eligibility criteria: 30 diabetic patient with chronic periodontitis with minimum 3 area in gingival sulcus with gingival probing depth more than 4 millimeter and less than 7 millimeter, selected. Systemic antibiotic user in 3 months before study, periodontal treatment user in 6 months before study, smokers, patients with acute medical problems, patients with less than 8 teeth in mouth, pregnant and nursing women exclude the study. Intervention: Case group receive conventional mechanical periodontal treatment include scaling and root planning with local application of 5% tetracycline gel (in periodontal treatment session gel is applied after scaling and root planning with syringe and remained in area with periodontal pack for 10 days) and oral hygiene education and control group receive conventional mechanical periodontal treatment with oral hygiene education. Main outcome measures (variables): Hematologic variables such as HbA1c and lipid profile are measured in the beginning of study and 3 months later and hematologic variables compare in two time of study and two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013092614774N1**

Registration date: **2014-02-06, 1392/11/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-02-06, 1392/11/17

Registrant information

Name

Yasin Asadi

Name of organization / entity

Shahid Sadoughi University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 35 1828 0454

Email address

y.asadi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

vice chancellor for research of Yazd Shahid Sadoughi Dental School

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of local application of tetracycline gel with SRP on HbA1c & lipid profile in type2 diabetic patients

Public title

Effects of SRP on blood glucose level reduction in diabetic patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Diabetic patients with moderate to good blood glucose control; patients with chronic periodontitis with minimum 3 area in gingival sulcus with periodontal probe depth more than 4mm and less than 7 mm Exclusion criteria: Antimicrobial and antibiotic user in last 3 months; recipients periodontal treatment in last 6 months; smokers; patients with less than 8 teeth; pregnant and nursing women; acute medical complications

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Shahid Sadoughi University of Medical Science

Street address

Shahid Sadoughi University of Medical Science, Bahoona square, Yazd

City

Yazd

Postal code

Approval date

2013-07-13, 1392/04/22

Ethics committee reference number

71427

Health conditions studied

1

Description of health condition studied

Chronic Periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic Periodontitis

2

Description of health condition studied

Diabetes Mellitus

ICD-10 code

E10, E11,

ICD-10 code description

Diabetes Mellitus

Primary outcomes

1

Description

HbA1c

Timepoint

At the beginning of the study & 3 months later

Method of measurement

A percent in patient`s hemmatology test

2

Description

Lipid profile

Timepoint

At the beginning of the study & 3 months later

Method of measurement

miligeram per deciliter in patient`s hemmatology test

Secondary outcomes

1

Description

Periodontal pocket depth

Timepoint

At the beginning of the study and 3 months later

Method of measurement

Millimeter and with using periodontal prob

2

Description

Plaque Index

Timepoint

At the beginning of the study and 3 months later

Method of measurement

A percent obtaine by placing colored surfaces of the teeth in O'Leary plaque index formula

3

Description

Gingival Index

Timepoint

At the beginning of the study and 3 months later

Method of measurement

A number between 1-4 according to gingival inflammation. it is completely observational

Intervention groups

1

Description

Control group: Scaling and rootplanning with ultrasonic scaler, Polishing with polish paste with low polish effect, patient education in beginning the study

Category

Treatment - Other

2

Description

Intervention group: Scaling and rootplanning with ultrasonic scaler, Polishing with polish paste with low polish effect, Patient education and after scaling and root planning, Local application of tetracycline hydrochloride 5% gel in gingival sulcus and application of periodontal pack on the tetracycline gel for 10 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Reserch Center

Full name of responsible person

Dr Mohammad Afkhami

Street address

Diabetes Reserch Center, Jomhori-E-Eslami boulevard, Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr Fatemeh Ezzoddini- vice chancellor for reasearch

Street address

Bahonar square, Yazd

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shahid Sadoughi University of Medical Sciences

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

Shahid Sadoughi Univercity of Medical Science

Full name of responsible person

Yasin Asadi

Position

Postgraduate student of periodontics

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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Full name of responsible person

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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