

# 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

##### Street address

Baran1 residential assembled, Safaeeye, Yazd

##### City

Yazd

##### Postal code

##### Phone

+98 35 1828 0454

##### Fax

##### Email

y.asadi@ssu.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Sadoughi University of Medical Science

##### Full name of responsible person

Yasin Asadi

##### Position

Postgraduate student of periodontology

##### Other areas of specialty/work

##### Street address

Baran1 residential assembled, Saffaeiye, Yazd

##### City

Yazd

##### Postal code

##### Phone

+98 35 1828 0454

##### Fax

##### Email

y.asadi@ssu.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Sadoughi University of Medical Science

**Full name of responsible person**

Yasin Asadi

**Position**

Postgraduate student of periodontology

**Other areas of specialty/work**

**Street address**

Baran1 residential assembled, Saffaeiye, Yazd

**City**

Yazd

**Postal code**

**Phone**

+98 35 1828 0454

**Fax**

**Email**

y.asadi@ssu.ac.ir yasin\_asadi63@yahoo.com

**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*