

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Evaluating the effect of sub-antimicrobial dose Doxycycline as an adjuvant on periodontal treatments in diabetics and non diabetics

Protocol summary

Summary

Objectives: Evaluating the effect of sub-antimicrobial dose Doxycycline as an adjuvant on periodontal treatments in diabetics and non diabetics Design: A non-randomized clinical trial, Study sample: 32 patients consist of 16 diabetic and 16 non diabetics. Inclusion criteria: Patients have at least 14 teeth, at least 8 pockets with PD (Probing Depth) ≥ 5 mm and CAL (Clinical Attachment Level) ≥ 4 mm, do not be sensitive to Doxycycline family, do not use interfering drugs with Tetracycline (Anti Coagulants and Oral Contraceptives) and do not have antibiotic therapy or periodontal therapy in 4 months ago. Intervention: The probing depth, clinical attachment level and bleeding on probing are recorded for diabetic and non diabetic patients. Following Scaling and root planning, patients are divided into intervention and control groups. Doxycycline 20 mg bid (every 12 hours) is prescribed for interventional groups of diabetic and non diabetic patients for 3 months. Main outcome: All clinical measurements (PD, CAL and BOP) are recorded again after 3 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013032212847N1**

Registration date: **2013-05-29, 1392/03/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-05-29, 1392/03/08

Registrant information

Name

Arezoo Khabazian

Name of organization / entity

Shahid Sadoghi University Of Medical Science

Country

Iran (Islamic Republic of)

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+98 35 1822 8852

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arezookhabazian@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

1- Doxycycline 20 mg from Dr Vahidi Draugstore 2- Other costs will pay by Shahid Sadoghi University of Medical Science, Yazd Dental School

Expected recruitment start date

2013-01-07, 1391/10/18

Expected recruitment end date

2013-05-05, 1392/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of sub-antimicrobial dose Doxycycline as an adjuvant on periodontal treatments in diabetics and non diabetics

Public title

The effect of Doxycycline on periodontal treatment in diabetics and non diabetics

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria include: Patients have at least 14 teeth, at least 8 pockets with PD (Probing Depth) ≥ 5 mm and CAL (Clinical Attachment Level) ≥ 4 mm, do not be sensitive to Doxycycline family, do not use interfering

drugs with Tetracycline (Anti Coagulants and Oral Contraceptives) and do not have antibiotic therapy or periodontal therapy in 4 months ago.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Indeed, this study is in the form of two Clinical Trial Studies, which are concurrently done in order to evaluate the effect of Doxycycline 20 mg on periodontal treatment of diabetic and non diabetic patients. Diabetic and non diabetic patients were randomly divided into two interventional and control groups, even numbers added to intervention group and odd numbers added to control group. The intervention in this study is Doxycycline capsules as scaling and root planning is done for all patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoghi University of Medical Science-Yazd Dental School

Street address

Yazd- Fazaye Sabz Square

City

Yazd

Postal code

Approval date

2013-01-06, 1391/10/17

Ethics committee reference number

171142160p

Health conditions studied

1

Description of health condition studied

Moderate to Severe Chronic Periodontitis

ICD-10 code

k05.3, E10

ICD-10 code description

Chronic Periodontitis, Diabetes Mellitus

Primary outcomes

1

Description

Probing depth

Timepoint

Before intervention and 3 months after intervention

Method of measurement

On millimeter scale and by William's probe

2

Description

Clinical attachment level

Timepoint

Before intervention and 3 months after intervention

Method of measurement

On millimeter scale and by William's probe

3

Description

Bleeding on probing

Timepoint

Before intervention and 3 months after intervention

Method of measurement

According to percentage of areas which have bleeding

Secondary outcomes

empty

Intervention groups

1

Description

Scaling and root planning is done by an ultrasonic device (China, Woodpecker) for diabetic patients in interventional group 1, then oral Doxycycline 20 mg which was made by a drugstore as much as need for this study is prescribed bid (every 12 hours) for 3 months. It is available in capsules by dose of 100 mg in Iran, but by mixing the content of 100 mg capsules with the starch doses of 20 mg has been identified.

Category

Treatment - Drugs

2

Description

Scaling and root planning is done by an ultrasonic device (China, Woodpecker) for diabetic patients in

interventional group 2.

Category

Treatment - Other

3

Description

Scaling and root planning is done by an ultrasonic device (China, Woodpecker) for non diabetic patients in interventional group 3, then Doxycycline 20 mg which was made by a drugstore is prescribed bid for 3 months.

Category

Treatment - Drugs

4

Description

Scaling and root planning is done by an ultrasonic device (China, Woodpecker) for non diabetic patients in interventional group 4.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabetes Research Center- Shahid Sadoghi University of Medical Science

Full name of responsible person

Street address

City

Yazd

2

Recruitment center

Name of recruitment center

Shahid Sadoghi University of Medical Science- Yazd Dental School

Full name of responsible person

Street address

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shahid Sadoghi University of Medical Science

Full name of responsible person

Dr Fatemeh Ezodini - Vice Chancellor for Research, Shahid Sadoghi University of Medical Science

Street address

Shahid Bamonar Sq. 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 Sadoghi University of Medical Science

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 Sadoghi University of Medical Science-Yazd Dental School

Full name of responsible person

Arezo Khabazian

Position

Doctor/ Post Graduate Student of Periodontics

Other areas of specialty/work

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Person responsible for scientific inquiries

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Shahid Sadoghi University of Medical Science-Yazd Dental School

Full name of responsible person

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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