

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of low dose Doxycycline as an adjunct to non-surgical periodontal therapy on the serum level of inflammatory mediators and lipid profile in advanced periodontitis

Protocol summary

Summary

The aim of this study is to evaluate the effect of periodontal treatment with or without low dose Doxycycline on circulating TNF - α , IL - 6, and serum Lipids in advanced periodontitis. Thirty four participants, aged 40-70 year-old, with severe generalized periodontitis are recruited from patients referred to the periodontics department, faculty of Dentistry, Guilan University of Medical Sciences. The patients are randomly assigned into control or intervention group to receive deep scaling and root planing, chlorhexidine mouthwash, and oral hygiene instruction as well as either placebo or 40 mg doxycycline capsule for one month. Serum level of inflammatory mediators as well as periodontal parameters including probing pocket depth, clinical attachment level, bleeding upon probing, and plaque index are measured (by a blind examiner) before and one month after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904071081N4**
Registration date: **2010-10-28, 1389/08/06**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-10-28, 1389/08/06

Registrant information

Name

Golpar Radafshar

Name of organization / entity

Guilan University of Medical Sciences, School of

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research, Guilan University of Medical Sciences,

Expected recruitment start date

2010-04-05, 1389/01/16

Expected recruitment end date

2010-06-06, 1389/03/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of low dose Doxycycline as an adjunct to non-surgical periodontal therapy on the serum level of inflammatory mediators and lipid profile in advanced periodontitis

Public title

Effect of low dose Doxycycline as an adjunct to non-surgical periodontal therapy on the serum level of inflammatory mediators and lipid profile in advanced periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 40 to 70 years , Being systemically

healthy with no history of Arthritis, GI disorders, skin diseases, bronchitis, Diabetes Mellitus, pregnancy or breast feeding, Body mass index between 20-27, Existence of at least 20 standing teeth without untreated periapical lesions, and at least 15% of sites with more than or equal to 5 mm of clinical attachment loss and evidence of bone loss in at least two quadrants. Exclusion criteria: Being under treatment with drugs such as: anticoagulants, steroids, anti-inflammatory drugs, immunosuppressant drugs within past 6 months, any periodontal treatment within past three months, heavy smokers

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Vice-chancellor for Research

Street address

Building of Guilan University of Medical Sciences,
Mellat St., Namjoo Blvd.

City

Rasht

Postal code**Approval date**

empty

Ethics committee reference number

40021

Health conditions studied**1****Description of health condition studied**

advanced periodontitis disease

ICD-10 code

K05.3

ICD-10 code description

Chronic Periodontitis

Primary outcomes**1****Description**

Serum inflammatory mediator: TNF- α

Timepoint

Baseline and one month after the intervention

Method of measurement

Laboratory test: ELIZA

2**Description**

Serum inflammatory mediator: IL-6

Timepoint

Baseline and one month after the intervention

Method of measurement

Laboratory test: ELIZA

3**Description**

Serum cholesterol levels

Timepoint

Baseline and one month after the intervention

Method of measurement

Routine laboratory tests

4**Description**

Serum level of LDL

Timepoint

Baseline and one month after the intervention

Method of measurement

Routine laboratory tests

5**Description**

Serum level of HDL

Timepoint

Baseline and one month after the intervention

Method of measurement

Routine laboratory tests

6**Description**

Serum triglyceride levels

Timepoint

Baseline and one month after the intervention

Method of measurement

Routine laboratory tests

Secondary outcomes

1

Description

periodontal parameter: Probing Pocket Depth

Timepoint

Baseline and one month after the intervention

Method of measurement

Calibrated periodontal probe

2

Description

Periodontal parameter: Clinical Attachment Level

Timepoint

Baseline and one month after the intervention

Method of measurement

Calibrated periodontal probe

3

Description

Periodontal parameter: Bleeding on probing

Timepoint

Baseline and one month after the intervention

Method of measurement

Bleeding points index (Lenox & Kopczyk)

4

Description

Dental Plaque

Timepoint

Baseline and one month after the intervention

Method of measurement

Oleary plaque index

Intervention groups

1

Description

Doxycycline one 40mg capsule per day plus intensive scaling and root planing

Category

Treatment - Drugs

2

Description

One placebo capsule per day plus intensive scaling and root planing

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Periodontology,School of dentistry,Guilan University of Medical Sciences

Full name of responsible person

Golpar Radafshar

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Opp. Pardis Hotel, Emam Khomeini Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research, Guilan University of Medical Sciences

Full name of responsible person

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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, Guilan 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

Department of Periodontology, Dental Research Center, School of Dentistry, Guilan University of Medi

Full name of responsible person

Nastaran Mirfarhadi

Position

MS in Nursing Education/Director of Dental Research Center

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