

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of non-surgical periodontal therapy on pentraxin-3 concentration in gingival crevicular fluid of chronic periodontitis patients

Protocol summary

Study aim

This study aim to assess the effect of non-surgical periodontal therapy on level of pentraxin-3 in gingival crevicular fluid of chronic periodontitis patients

Design

The control group consists of 25 healthy individuals between 25 to 50 years who had no history of periodontal disease. The patient group comprise of 25 patients with generalized moderate chronic periodontitis between 25 to 50 years.

Settings and conduct

Gingival crevicular fluid (GCF) samples collect from the patients and controls, who visit the periodontology department at Qazvin University of Medical Sciences, using paper strips to assess the level of pentraxin-3. In the patient group, GCF samples collect again 6 weeks after scaling and root planing from the same area. All samples are coded and blindly send to the laboratory. The level of pentraxin-3 in the GCF is quantified using enzyme-linked immunosorbent assay.

Participants/Inclusion and exclusion criteria

The control group consists of 25 healthy individuals between 25 to 50 years who had no history of periodontal disease. The patient group comprise of 25 patients with generalized moderate chronic periodontitis between 25 to 50 years. The exclusion criteria are systemic conditions such as respiratory and cardiovascular diseases, diabetes mellitus, HIV, chemotherapy, pregnancy or nursing, antibiotic therapy, medication intake, periodontal treatment in the past 6 months, smoking, infectious diseases and any sign/symptom of infection.

Intervention groups

Scaling and root planing in the patient group

Main outcome variables

Compare the level of pentraxin-3 of patients before treatment with control group : Compare the level of pentraxin-3 of patients before treatment with 6 weeks after treatment : Compare the level of pentraxin-3 of

patients 6 weeks after treatment with control group :
Compare periodontal indices with laboratory findings

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190717044253N1**

Registration date: **2019-08-28, 1398/06/06**

Registration timing: **retrospective**

Last update: **2019-08-28, 1398/06/06**

Update count: **0**

Registration date

2019-08-28, 1398/06/06

Registrant information

Name

Mahtab Samieifar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-10, 1396/06/19

Expected recruitment end date

2017-12-10, 1396/09/19

Actual recruitment start date

2017-09-22, 1396/06/31

Actual recruitment end date

2017-12-20, 1396/09/29

Trial completion date

2018-02-09, 1396/11/20

Scientific title

Effect of non-surgical periodontal therapy on pentraxin-3 concentration in gingival crevicular fluid of chronic periodontitis patients

Public title

Pentraxin-3 concentration in gingival crevicular fluid

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

25 to 50 years Patients with moderate periodontitis (patient group) No history of periodontal disease (control group)

Exclusion criteria:

Systemic conditions such as respiratory and cardiovascular diseases, diabetes mellitus, HIV, chemotherapy, pregnancy or nursing Antibiotic therapy, medication intake in the past 6 months, Smokers Infectious diseases and any sign/symptom of infection. Periodontal treatment in the past 6 months

Age

From **25 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ethics committee of Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Bahonar Blvd, Qazvin, Iran

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3419915315

Approval date

2017-07-10, 1396/04/19

Ethics committee reference number

IR.QUMS.REC.1396.188

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

Generalized moderate chronic periodontitis

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Level of pentraxin-3 in gingival crevicular fluid

Timepoint

At the beginning of the study and 6 weeks after scaling and rootplaning

Method of measurement

enzyme-linked immunosorbent assay

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: receive no treatment.

Category

Diagnosis

2**Description**

Participants receive oral hygiene instructions (the rolling method twice a day) .Phase I periodontal therapy is performed for periodontitis patients in two sessions with a one-week interval, and includes scaling and root planing with hand and ultrasonic instruments. No antibiotic or anti-inflammatory agent is prescribed for patients. Periodontitis patients are recalled six weeks after the second treatment session. Gingival crevicular fluid is collected again from the same area and clinical parameters are measured again. All procedures will be performed by the same operator . The patients are recalled two weeks after the second scaling session and their adherence to oral hygiene instructions is evaluated. Supragingival prophylaxis is also performed for them .

Gingival crevicular fluid is collected using Periopaper .
Paper strip is inserted into the gingival crevice and
remained there for one minute.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Periodontology department of Qazvin University of
Medical Sciences

Full name of responsible person

Mahtab Samieifar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Qazvin University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mahtab Samieifar

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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**Person responsible for scientific
inquiries**

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information exists.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available