

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Non-Surgical Treatment on Interleukin-17 and Interleukin-23 level in Gingival Crevicular Fluid in patients with periodontitis

Protocol summary

Study aim

Effects of Non-Surgical Treatment on Interleukin-17 and Interleukin-23 level in Gingival Crevicular Fluid in patients with chronic and aggressive periodontitis
Determination of the initial values of the two cytokines
Determination of the amounts of these two cytokines after treatment

Design

clinical trial, Non randomized sampling, sample size was calculated based on similar studies: 18 individuals in aggressive group and 18 individuals in chronic group.

Settings and conduct

The study participants will be selected from individuals affected by periodontitis, referred to the Department of Periodontics, Faculty of Dentistry, Shahed University, Tehran, Iran. Gingival Crevicular Fluid will be harvested before and after initial phase of periodontal treatment. Cytokine concentration will be assessed by ELISA test.

Participants/Inclusion and exclusion criteria

inclusion criteria: individuals with chronic and aggressive periodontitis
exclusion criteria: periodontal treatment within the previous six months, use of any antibiotics /or immunosuppressive drugs in the past 3 months, history of any systemic disease, smoking.

Intervention groups

Control group is the same individuals before scaling and root-planning therapy. scaling and root-planning therapy will be done for all participant.

Main outcome variables

interleukin-17 level and interleukin-23 levels in chronic and aggressive periodontitis; The effect of phase I periodontal therapy on the level of interleukin-17 and interleukin-23

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180729040623N1**

Registration date: **2018-08-16, 1397/05/25**

Registration timing: **retrospective**

Last update: **2018-08-16, 1397/05/25**

Update count: **0**

Registration date

2018-08-16, 1397/05/25

Registrant information

Name

Fereshteh Shanei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 9210

Email address

fr.shanei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2013-10-01, 1392/07/09

Expected recruitment end date

2014-10-22, 1393/07/30

Actual recruitment start date

2013-10-01, 1392/07/09

Actual recruitment end date

2014-12-01, 1393/09/10

Trial completion date

empty

Scientific title

Effects of Non-Surgical Treatment on Interleukin-17 and Interleukin-23 level in Gingival Crevicular Fluid in patients with periodontitis

Public title

effect of periodontal treatment on IL-17 and IL-23

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

systematically healthy individuals with chronic or aggressive periodontitis

Exclusion criteria:

history of periodontal treatment within the previous six months, , use of any antibiotics /or immunosuppressive drugs in the past 3 months consumption of any kind of medicine which affects periodontium (including medicine which cause gingival enlargement). pregnancy smoking any immunosuppressive,metabolic or systemic disease

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Actual sample size reached: **54**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Clinical Ethics Committee of Shahed University

Street address

around the shrine of Imam Khomeini, Persian Gulf,Tehran

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2015-05-29, 1394/03/08

Ethics committee reference number

IR.Shahed.REC.1394.297

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

Aggressive periodontitis

ICD-10 code

K05.2

ICD-10 code description

Aggressive periodontitis

Primary outcomes

1

Description

Interleukin-17 level

Timepoint

before scaling and root-planning and 6 weeks after intervention

Method of measurement

ELISA test

2

Description

Interleukin-23 level

Timepoint

before scaling and root-planning and 6 weeks after intervention

Method of measurement

ELISA test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All subjects participating in the study are subject to scaling and root-planning treatment, The same people are in control group before the intervention. So there is only one intervention group.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental branch of Shahed university

Full name of responsible person

Ferial Taleghani

Street address

NO. 39, Italy St,Vesal St, District 6, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Seyed mohammad reza Hakimaneh

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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

Shahed University

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

Person responsible for general inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Fereshteh Shanei

Position

Resident

Latest degree

Subspecialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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Full name of responsible person

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Fax**Email**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available