Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of IL-1alpha and TNF-alpha levels in saliva of patients with Chronic periodontitis before and after Scaling and Root Planing

Protocol summary

Summary

This study is going to investigate the effect of non-surgical treatment on salivary concentration of two proinflammatory mediators, TNF-alpha and IL-1alpha. Thirty subjects with chronic periodontitis and 30 subjects without any periodontal problem, according to inclusion and exclusion criteria, will be selected to participate in this study. Inclusion criteria: Healthy subjects; having at least 18 years old and more than 20 teeth. Exclusion criteria is pregnancy, lactation, history of antibiotics or NSAIDs intake, presence of inflammatory mucosal lesions, smoking and alcohol abuse. Intervention include Scaling and root planing. Unstimulated saliva will be collected before Scaling and root planing and 30 days after intervantion. Periodontal parameters like pocket depth, clinical attachment loss and bleeding on probing will be recorded and samples will be collected to evaluate periodontal situation and response to treatment. Saliva samples of control group will be collected too. After centrifuging and aliquoting saliva samples they will kept at -20 temperature until ELISA test will be done on samples. Change in the concentrations of TNF-alpha and IL-1alpha is expected.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052825649N3**
Registration date: **2016-06-07, 1395/03/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-06-07, 1395/03/18

Registrant information

Name

Masoome Eivazi

Name of organization / entity

Kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Kermanshah University of Medical Sciences

Expected recruitment start date

2016-02-09, 1394/11/20

Expected recruitment end date

2016-05-04, 1395/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of IL-1alpha and TNF-alpha levels in saliva of patients with Chronic periodontitis before and after Scaling and Root Planing

Public title

The effect of Scaling and Root Planning on level of TNF-alpha and IL-1alpha of saliva

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Subjects with chronic periodontitis; Subjects with periodonta healthy; being healthy.
Exclusion criteria : Subjects with systemic disorders

(e.g.,diabetes mellitus, asthma); Pregnancy and Lactation; Having Less than 20 teeth; Use of antibiotics during last month; History of continuous consumption of NSATDs; Smoking , Alcohol abuse; History of periodontal treatments during one previous year; Subjects with inflammatory mucosal lesions (Lichen Planus) and Salivary gland disease

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Ethics Committe of Kermanshah University of Medical Sceinces,Shahidbeheshti Blvd

City

Kermanshah

Postal code

Approval date

2016-05-25, 1395/03/05

Ethics committee reference number

KUMS.REC.1395.128

Health conditions studied

1

Description of health condition studied

Chronic Periodontitis

ICD-10 code

k05.3

ICD-10 code description

chronic periodontitis

Primary outcomes

1

Description

Interleukin-1alpha

Timepoint

At the time of scaling and 30 days after it

Method of measurement

ELISA kit

2

Description

Tumor Necrosis Factor alpha

Timepoint

At the time of scaling and 30 days later

Method of measurement

ELISA kit

Secondary outcomes

1

Description

Pocket depth

Timepoint

At the time of scaling and 30 days later

Method of measurement

measuring the distance of pocket base to the gingval margin using periodontal probe

2

Description

Clinical Attachment Loss

Timepoint

At the time of scaling and 30 days later

Method of measurement

measuring the distance of base of the pocket from CEJ

3

Description

Bleeding during Probing

Timepoint

At the time of scaling and 30 days later

Method of measurement

Observation

4

Description

Plaque Index

Timepoint

At the time of scaling and 30 days later

Method of measurement

Observation

Intervention groups

1

Description
Intervention group: Non-Surgical Treatment (Scaling and Root Planning)
Category
Treatment - Other

2

Description
Control group: observation
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Periodontics,Dentistry school, Kermanshah University of Medical Sciences
Full name of responsible person
Masoome Eivazi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Kermanshah University of Medical Sciences
Full name of responsible person
Kourosh Hamzeei
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Kermanshah
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 of Kermanshah 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
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Person responsible for updating data

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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