Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of effect scaling and root planning on the Trichomonas tenax and Entomoeba gingivalis in patients with chronic periodontitis

Protocol summary

Summary

This study will be done to evaluate the effect of phase I periodontal (oral hygiene instructions, scaling and root planning) to determine frequency of “Trichomonas tenax” and “Entomoeba gingivalis” in saliva and plaque samples of patients before intervention and 3 weeks after that. The studied population includes patients suffering from moderate to severe chronic periodontitis who referred to Dental college of Yazd. After determining the severity of disease, patients randomly are categorized into two groups named case and control using a table of random numbers. Sampling will be done in two phase, during a 3 weeks interval. Control group will be received oral hygiene instructions; phase I periodontal will be done on case group after first sampling. The second samples will be prepared and sent to the Parasitology lab after 3 weeks. During the study, the person who collects saliva and dental plaque is not aware of presence and frequency of these oral parasites and this study is a single blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014071013167N4**
Registration date: **2014-09-09, 1393/06/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-09-09, 1393/06/18

Registrant information

Name

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Name of organization / entity

Shahid Sadoughi University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2014-07-19, 1393/04/28

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect scaling and root planning on the Trichomonas tenax and Entomoeba gingivalis in patients with chronic periodontitis

Public title

Effect of scaling and root planning on two types of parasites, Trichomonas tenax and Entomoeba gingivalis in patients with chronic periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Persons between the ages of 30 to 55 years, no history of periodontal treatment (scaling) in the past six months, no history of antibiotic therapy within the previous three months and not taking effective drugs on periodontium (medications that suppress the immune system, reducing hypertension, anticonvulsants,

contraceptives, etc.), lack of systemic diseases such as diabetes or heart disease, no pregnancy, no smoking or other drug abuser; Exclusion criteria: those who do not have the entry criteria and who after baseline sampling do not return after three weeks

Age

From **63 years** old to **38 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

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

Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Sciences, Bahonar Squ,Yazd,Iran

City

Yazd

Postal code

89195/165

Approval date

2014-05-03, 1393/02/13

Ethics committee reference number

17/1/31877/پ

Health conditions studied

1

Description of health condition studied

chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic pericoronitis Periodontitis: NOS complex simplex

Primary outcomes

1

Description

Frequency of Trichomonas tenax and Entomoeba gingivalis

Timepoint

Before intervention (oral education instruction, scaling and root planning) and three weeks after that

Method of measurement

Saliva and plaque are collected by pipet and sterile curette respectively. Collected samples are fixed then are prepared by Giemsa staining and read ¼ of Prepared smear whit optical microscope

Secondary outcomes

1

Description

Pocket depth

Timepoint

Before and three weeks after the intervention

Method of measurement

Millimeters

2

Description

Bleading on probing

Timepoint

Before and three weeks after the intervention

Method of measurement

A percent by Gingival Sulcus Bleeding Index

Intervention groups

1

Description

Intervention group: phase I of periodontal treatment (oral hygiene instruction, scaling and root planning)

Category

Prevention

2

Description

Control group: oral hygiene instruction

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Periodontics, Shahid Sadoughi Dentistry University

Full name of responsible person

Dr.Fahimeh Rashidi Meibodi
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Dentistry University, Dahe Fajr Blvd, Yazd, Iran
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Sponsors / Funding sources

1

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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
Shahid Sadoughi 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

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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