

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effect of non-invasive periodontal therapy(SRP) on levels of salivary biomarkers of mmp7 and mucin4 in patients with moderate to severe chronic periodontitis

Protocol summary

Study aim

Determination of the effect of scaling on the amount of saliva mp7 and mp4 biomarkers in patients with moderate to severe chronic periodontitis

Design

A clinical trial with a community-based control group was performed randomly.

Settings and conduct

A study was conducted at the dental clinic of Bushehr University of Medical Sciences. In this clinical trial study, 40 patients in the age group of 30-60 years old were randomly assigned to two groups according to the criteria for entering and leaving the study. Patients in both groups receive saliva samples before each intervention. Patients are asked to spray their non-stimulated saliva in sterile microtiles for 2 minutes. Saliva samples to determine the enzyme concentration in the biochemical laboratory Transferred and centrifuged for 10 minutes at 4 ° C and freeze-dried immediately after removal of the supernatant at -40 ° C until the measurements are carried out. Then, for the group of patients (intervention group), the scaling procedure (as the main intervention intervention), along with oral hygiene education (OHI), as well as the daily administration of 10 mg daily chlorhexidine degluconate solution for 2 weeks, for one week For the second group (control group), only oral health education (OHI) and mouthwash administration are presented with a similar pattern to the intervention group. Patients in both groups receive saliva samples again one month after the intervention, and in both patients the clinical status of periodontitis is evaluated.

Participants/Inclusion and exclusion criteria

Patients aged 30-60 years with moderate to severe chronic periodontitis

Intervention groups

Patients aged 30-60 years with moderate to severe

chronic periodontitis

Main outcome variables

mucin4; mmp7

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180521039761N1**

Registration date: **2018-08-25, 1397/06/03**

Registration timing: **retrospective**

Last update: **2018-08-25, 1397/06/03**

Update count: **0**

Registration date

2018-08-25, 1397/06/03

Registrant information

Name

najmeh shooraki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 3332 3226

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

2018-05-22, 1397/03/01

Actual recruitment end date

2018-07-23, 1397/05/01

Trial completion date

empty

Scientific title

Evaluation of the effect of non-invasive periodontal therapy(SRP) on levels of salivary biomarkers of mmp7 and mucin4 in patients with moderate to severe chronic periodontitis

Public title

Evaluation of the effect of SRP on levels of salivary biomarkers of mmp7 and mucin4 in patients with moderate to severe chronic Tissue Inflammation

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with moderate to severe periodontitis from 30 to 60 years of age

Exclusion criteria:

Pregnancy History of smoking and alcohol Chronic inflammatory diseases of the skin and oral mucosa Systemic diseases that affect periodontal conditions Periodontal acute diseases such as periodontal abscesses Radiographic evidence of visible bone resorption in posterior B.W

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The study samples were selected based on the criteria for entering and leaving the study. For random allocation random sampling, two groups of intervention and control group were used.

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 bushehr university of medical sciences

Street address

Dental clinic; Heidari ave.

City

bushehr

Province

Boushehr

Postal code

7514633341

Approval date

2018-03-12, 1396/12/21

Ethics committee reference number

IR.BPUMS.REC.1396.203

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

Moderate to severe chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

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

MUCIN4/MMP7

Timepoint

Before starting the study and one month later

Method of measurement

ELISA Kit

Secondary outcomes

empty

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

Intervention group: A group of patients for whom oral contraceptive practice (OHI) and oral administration of 2 ml of 10 ml of .2% chlorhexidine d-gluconate solution are administered for one week for oral administration.

Category

Diagnosis

2**Description**

Control group: For the control group, only Oral Hygiene (OHI) and oral chloride.2% are prescribed. Patients are

asked to refer to the saliva for one month after receiving saliva

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Bushehr university of medical sciences

Full name of responsible person

Najmeh shooraki

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr 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?

No

Title of funding source

Bushehr 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

Boushehr University of Medical Sciences

Full name of responsible person

Najmeh Shooraki

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

0

When the data will become available and for how long

0

To whom data/document is available

0

Under which criteria data/document could be used

0

From where data/document is obtainable

0

What processes are involved for a request to access data/document

0

Comments

0