

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparing of the effect of scaling and rootplaning on the periodontal condition of hemodialysis and normal patients

Protocol summary

Study aim

Measuring the improvement rate of periodontal condition after SRP in dialysis patients and comparing it with the rate of improvement in healthy people

Design

Clinical trials with control group (30 healthy subjects with chronic to severe periodontitis), one side blind, so patients are unaware of the design and purpose of the study. After completing a list of people with entry requirements, the excel program selected thirty individuals selectively for each group (total is sixty). The number of samples was calculated with the mean comparison formula with the view of Tabibzadeh Nuri (2006).

Settings and conduct

In this clinical trial study, 30 systematic healthy patients with chronic periodontitis (control group) and 30 dialysis patients with chronic periodontitis (case group) were divided into two groups and received written consent after obtaining written consent. After oral health education and when PI (dental plaque index) was below 30%, in each of the two groups, periodontal examination that concluding the PD (periodontal packet depth) and CAL (clinical attachment loss) was performed. Each of the two groups received non-surgical periodontal treatment(SRP). Periodontal examinations were repeated again after 4 and 8 weeks.

Participants/Inclusion and exclusion criteria

All people must need to SRP (moderate to sever periodontitis) good coagulation condition Having at least one molar teeth and one first premolar tooth and two anterior teeth in each jaw Having at least 1 area with a pocket depth of 3 mm and more in at least 2 quadrants of the mouth

Intervention groups

People undergoing hemodialysis and suffering from chronic periodontitis Individuals are systemically healthy and have chronic periodontitis intervention is scaling and root planing and health education

Main outcome variables

CAL values Depth of pocket probe

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190422043346N1**

Registration date: **2019-06-27, 1398/04/06**

Registration timing: **retrospective**

Last update: **2019-06-27, 1398/04/06**

Update count: **0**

Registration date

2019-06-27, 1398/04/06

Registrant information

Name

Ali Naghavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3462 3647

Email address

alingv94@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-03, 1397/11/14

Expected recruitment end date

2019-04-09, 1398/01/20

Actual recruitment start date

2019-02-05, 1397/11/16

Actual recruitment end date

2019-04-25, 1398/02/05

Trial completion date

2019-04-25, 1398/02/05

Scientific title

Comparing of the effect of scaling and rootplaning on the periodontal condition of hemodialysis and normal patients

Public title

effect of SRP on hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years INR less than 4 Having at least one premolar molar and two anterior teeth in each quadrant of mouth Having at least one area with a depth of 3 mm and more in at least 2 quadrants from the mouth The presence of a zone with a lashing attachment greater than 2 mm plaque Index(PI) below 30% They are currently being treated for dialysis and having a minimum of three months of dialysis (for the case group) Availability of Persons and Written Satisfaction

Exclusion criteria:

Pregnancy Get periodontal treatment (SRP) in the last 6 months The presence of a systemic disease that affects the periodontal condition smoking

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

N/A

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

Single blinded

Blinding description

After enrolling patients and placing them in their own groups, they receive scaling and root planning by a clinician. All calculations on the day of treatment (before treatment), week 4 and 8 after treatment will be done by another clinician, this clinician has no information about the totality of the treatment that received by the patient.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of birjand University of Medical Sciences

Street address

Ghaffari Blvd , Birjand university of medical science

City

birjand

Province

South Khorasan

Postal code

0000000000

Approval date

2019-01-30, 1397/11/10

Ethics committee reference number

IR.BUMS.REC.1397.326

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

patient undergoing hemodialysis

ICD-10 code

Z49.01

ICD-10 code description

Encounter for fitting and adjustment of extracorporeal dialysis catheter

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

periodontal pocket depth

Timepoint

At the beginning of the study, four weeks and eight weeks after the intervention

Method of measurement

periodontal prob of WHO in mili meter

2**Description**

clinical attachment loss

Timepoint

At the beginning of the study, four weeks and eight weeks after the intervention

Method of measurement

periodontal prob of WHO in mili meter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention and case group: scaling and root planing and mouth health education. Before starting the treatment, the patients were given the same health education and they were asked to use dental floss to clean the interdental surfaces and then use the tooth brush (Soft 35) and toothpaste twice a day. One week later, all Dental calculations (6 areas in each tooth including Mesioabacal Midbacal Distobacal mesiolingual Mid Lingual and Distolingual) were performed. Clinical calculations were performed to determine the depth of the pocket probing (PPD) and determine the clinical attachment loss (CAL) in millimeters in 6 areas of Ramford teeth (teeth 16, 21, 24, 36, 41, 44). Then the samples received scaling treatment. scaling (SRP) is the removal of calculus and fragments of contaminated cementios from the root to provide a smooth, hard, and free surface.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Special Patients hospital of Birjand

Full name of responsible person

Tuba Kazemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor's Office for Research of birjand university of medical science

Full name of responsible person

Tuba Kazemi

Street address

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Grant name

3550000 rial

Grant code / Reference number

0

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Chancellor's Office for Research of birjand university of medical science

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

Birjand University of Medical Sciences

Full name of responsible person

Ali Naghavi

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The whole potential data is publishable after being unidentifiable

When the data will become available and for how long

Starting the access period from 2020

To whom data/document is available

Researchers working in academia and those involved in the industry can receive for data.

Under which criteria data/document could be used

Any use and analysis of the data in this study is allowed

From where data/document is obtainable

alingv94@gmail.com +989024926756 ali naghavi

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

After requesting the data, the email will be sent to the applicant in less than three days.

Comments