

# 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 Mesio-buccal Mid-buccal Distobuccal 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 Ramfjord 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 cementum 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

#### Street address

No. 3 , beheshti Ave.

#### City

birjand

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South Khorasan

#### Postal code

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#### Phone

+98 56 3221 3595

#### Email

azizi.m@bums.ac.ir

## 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

Birjand university of medical science Ghaffari Blvd.

#### City

Birjand

#### Province

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#### Postal code

9717853577

#### Phone

+98 56 3239 5000

#### Fax

#### Email

public\_r@bums.ac.ir

#### 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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#### Province

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#### Email

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Birjand University of Medical Sciences

**Full name of responsible person**

Ali Naghavi

**Position**

student

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

Birjand University of Medical Sciences

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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**