

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Evaluation Of The Effect Of Chronic Periodontitis Treatment On Changes In Vitamin D Serum Level Before And After Periodontal Treatment

#### Protocol summary

##### Study aim

Determining the effect of chronic periodontitis treatment on the changes in vitamin D serum level before and after periodontal treatment

##### Design

a single-arm clinical trial with a sample size of 38 patients

##### Settings and conduct

Patients from the periodontics department of Gilan Dental School are included in the study. Serum vitamin D levels of patients are measured and periodontal Scaling and Root Planing treatment and, if necessary, surgical treatment are performed for patients. 1 month and 3 months after periodontal treatment, the serum level of vitamin D will be measured again and its level will be compared with the level before periodontal treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include patients with untreated chronic periodontitis and having at least 6 teeth for each patient; Exclusion criteria include having a systemic disease that affects bone metabolism, having a history of cancer, consuming vitamin D and calcium supplements, consuming interfering drugs such as bisphosphonates, barbiturates, cardiac glycosides, cholestyramine, glucocorticoids, and laxatives, being pregnant and has a history of antibiotic therapy and periodontal treatment in the past 6 months.

##### Intervention groups

First, the indices of probe depth and clinical bone loss, index plate and radiographic bone loss of each patient are recorded. A blood sample is taken from the intervention group, and then periodontal treatment of scaling and leveling of the root surface and, if necessary, surgical treatment such as curettage or grafting are performed. One month later and three months later, the indicators are recorded again and the blood sample is taken from the patient.

##### Main outcome variables

Serum 25(OH)D3 level; periodontal therapy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240212060975N1**

Registration date: **2024-03-02, 1402/12/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-03-02, 1402/12/12**

Update count: **0**

##### Registration date

2024-03-02, 1402/12/12

##### Registrant information

##### Name

Amin Rajabzadeh Kanafi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3348 6418

##### Email address

a\_rajabzadeh@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-13, 1402/11/24

##### Expected recruitment end date

2024-07-14, 1403/04/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation Of The Effect Of Chronic Periodontitis Treatment On Changes In Vitamin D Serum Level Before And After Periodontal Treatment

#### Public title

Evaluation Of The Effect Of Chronic Periodontitis Treatment On Changes In Vitamin D Serum Level Before And After Periodontal Treatment

#### Purpose

Diagnostic

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with untreated chronic periodontitis Having at least 6 teeth for each patient

##### Exclusion criteria:

Having a systemic disease that affects bone metabolism  
Having a history of cancer  
Taking vitamin D and calcium supplements  
Users of interfering drugs such as Bisphosphonates, Barbiturates, Cardiac Glycosides, Cholestyramine, Glucocorticoids, and Laxatives  
Being pregnant  
Having a history of antibiotic therapy and periodontal treatment in the last 6 months

#### Age

No age limit

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 38

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Single

#### Other design features

Single-arm Clinical trial

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Gilan University of Medical Sciences

##### Street address

Guilan University Of Medical Sciences, Namjoo Blv.

##### City

Rasht

##### Province

Guilan

#### Postal code

33697-41938

#### Approval date

2024-01-31, 1402/11/11

#### Ethics committee reference number

IR.GUMS.REC.1402.574

## 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

25(OH)D3 Serum Level

#### Timepoint

Before periodontal treatment, 1 month after and 3 months after periodontal treatment

#### Method of measurement

Serum vitamin D level measurement by Razi Pathobiology Laboratory of Rasht

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

A total of 38 patients with chronic periodontitis with entry criteria from the periodontics department of Gilan Dental School were included in the study. First, the indices of probe depth and clinical bone loss, index plate and radiographic bone loss of each patient are recorded. A blood sample will be taken from the intervention group to evaluate the vitamin D serum level, and then periodontal treatment of scaling and leveling of the root surface and, if necessary, surgical treatment such as curettage or grafting will be performed. One month later and three months later, indicators are recorded again, blood samples are taken from the patient, and the effect of periodontal treatment on changes in vitamin D serum level is checked.

#### Category

Diagnosis

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Department of Periodontics of Guilan Faculty of Dentistry

**Full name of responsible person**

Amin Rajabzadeh Kanafi

**Street address**

Faculty of Dentistry, Guilan University of Medical Sciences, Fuman-Saravan Rd.

**City**

Rasht

**Province**

Guilan

**Postal code**

4194173774

**Phone**

+98 13 3348 6407

**Email**

dental@gums.ac.ir

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Ramyar Farzan

**Street address**

Research Vice-Chancellor of the University, Shahid Siyadati St., Namjoo Blv.

**City**

Rasht

**Province**

Guilan

**Postal code**

4144666949

**Phone**

+98 13 3333 5821

**Email**

research@gums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Rasht 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**

Rasht University of Medical Sciences

**Full name of responsible person**

Amin Rajabzadeh Kanafi

**Position**

Assistant Professor of Periodontology

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Faculty of Dentistry, Guilan University of Medical Sciences, Saravan-Fuman Rd., Rasht.

**City**

Rasht

**Province**

Guilan

**Postal code**

4194173774

**Phone**

+98 13 3348 6418

**Fax****Email**

a\_rajabzadeh@gums.ac.ir

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Amin Rajabzadeh Kanafi

**Position**

Assistant Professor of Periodontology

**Latest degree**

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### Person responsible for updating data

**Contact****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be 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**

Part of the data, such as the information related to the main outcome, can be shared.

**When the data will become available and for how long**

The access period starts 6 months after the results are published.

**To whom data/document is available**

Researchers working in academic and scientific institutions can apply to receive data.

**Under which criteria data/document could be used**

If there are titles in measuring the relationship between microparticles such as vitamin D and diseases such as periodontitis, the results can be used.

**From where data/document is obtainable**

Applicants can call Yasmin Saadat Rouhi on 09111317821 or send their application to info.saadatrouhi@gmail.com.

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

The applicant, by calling the mobile number 09111317821 in the name of Yasmin Saadat Rouhi, put forward his request and the conditions of its use and explain in what other conditions there will be for the use of these data or documents. During the call, the requester's email will be received, and after checking, the data files will be emailed to the requester within two to three days.

**Comments**