

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

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

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4194173774

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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.

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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

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

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Amin Rajabzadeh Kanafi

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Person responsible for updating data

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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