

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the Effect of Short-Term Use of Vitamin D with Vitamin D Plus Calcium Supplement in Treatment of Patients with Periodontitis Referred to Qom Dental School from 2021 to 2022

Protocol summary

Study aim

Determine the impact of Short-Term Use of Vitamin D with Vitamin D Plus Calcium Supplement in Treatment of Patients with Periodontitis Referred to Qom Dental School from 2021 to 2022

Design

The clinical trial has a control group based on parallel groups. Assignment of patients to three groups receiving vitamin D and SRP, vitamin D and calcium and SRP and SRP will be done by block method alone and using 6 blocks.

Settings and conduct

Individuals who have referred to the periodontics department of Qom Dental School will enter the study after obtaining informed consent.

Participants/Inclusion and exclusion criteria

Inclusion criteria: people with an average age of 20 to 70 years old. They have more than 20 teeth left in his mouth. At least two interproximal areas with CAL (clinical attachment level) more than 3 mm. Exclusion criteria: people with systemic problems such as diabetes, hypothyroidism or hyperthyroidism and any endocrine-related diseases. Severe systemic diseases such as cancer. Consumption of vitamin D and calcium during the three months before the study. Pregnancy and lactation. People who have received non-surgical periodontal treatment or periodontal surgery in the past year. Use of antibiotics and immunosuppressive drugs that affect the metabolism of vitamin D and calcium.

Intervention groups

Interventions: patients with chronic periodontitis whose vitamin level is less than 32 ng / ml are included in the study. For all patients, Scaling & Root Planning of the whole mouth and then health education is done similarly by flossing and brushing with modified Bass. Then, after two weeks, the first group is given 50,000 IU weekly vitamin D and 1,000 mg of daily calcium supplement,

and the second group is given only 50,000 IU weekly vitamin D for 3 months, and the third group as the control group is not given any medication.

Main outcome variables

Periodontal clinical parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210510051255N1**

Registration date: **2021-07-05, 1400/04/14**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-05, 1400/04/14**

Update count: **0**

Registration date

2021-07-05, 1400/04/14

Registrant information

Name

Fateme Abedini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3660 2455

Email address

dentistryabedini74@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effect of Short-Term Use of Vitamin D with Vitamin D Plus Calcium Supplement in Treatment of Patients with Periodontitis Referred to Qom Dental School from 2021 to 2022

Public title

Comparing the Effect of Short-Term Use of Vitamin D with Vitamin D Plus Calcium Supplement in Treatment of Patients with Periodontitis Referred to Qom Dental School from 2021 to 2022

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People with an average age of 20 to 70 years old They have more than 20 teeth left in his mouth At least two interproximal areas with CAL (clinical attachment level) more than 3 mm.

Exclusion criteria:

People with systemic problems such as diabetes, hypothyroidism or hyperthyroidism and any endocrine-related diseases Severe systemic diseases such as cancer Consumption of vitamin D and calcium during the three months before the study Pregnancy and lactation People who have received non-surgical periodontal treatment or periodontal surgery in the past year Use of antibiotics and immunosuppressive drugs that affect the metabolism of vitamin D and calcium

AgeFrom **20 years** old to **70 years** old**Gender**

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **51****Randomization (investigator's opinion)**

Randomized

Randomization description

Assigning patients to three groups receiving vitamin D and SRP, vitamin D and calcium, and SRP and SRP alone. It will be done by blocking method and using 6 blocks. Patients are divided into three groups using a randomized balanced block method with a block size of 6. A random sequence is created by an epidemiologist by running an online application on the website (<https://www.sealedenvelope.com>)

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Qom University of Medical Sciences

Street address

No. 83, Jihad Daneshgahi Alley, Shahid Lotfi Niasar (Alley No. 4), Safashahr St.

City

Qom

Province

Ghoum

Postal code

37169-93456

Approval date

2021-05-02, 1400/02/12

Ethics committee reference number

IR.MUQ.REC.1400.035

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

Periodontitis

ICD-10 code

K05.32

ICD-10 code description

Chronic periodontitis, generalized

2**Description of health condition studied**

Vitamin D deficiency

ICD-10 code

E55

ICD-10 code description

Vitamin D deficiency

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

Probing depth

Timepoint

Baseline, three months later

Method of measurement

Periodontal probe

2

Description

Clinical attachment loss

Timepoint

Baseline, three months later

Method of measurement

Periodontal probe

3

Description

Bleeding on probing

Timepoint

Baseline, three months later

Method of measurement

Periodontal probe

4

Description

Plaque index

Timepoint

Baseline, three months later

Method of measurement

Determination of plaque score according to O'Leary method

5

Description

Gingival index

Timepoint

Baseline, three months later

Method of measurement

Observation

Secondary outcomes

1

Description

25-hydroxyvitamin D

Timepoint

During the study

Method of measurement

Venous blood sampling

Intervention groups

1

Description

The first Intervention group: Scaling & Root Planning of the whole mouth and then hygiene training is done similarly by flossing and brushing with the modified Bass method. After two weeks of SRP, Prescribe 50,000 IU of vitamin D weekly and 1,000 mg of calcium supplement daily.

Category

Treatment - Drugs

2

Description

The second intervention group: Scaling & Root Planning of the whole mouth and then hygiene training is done similarly by flossing and brushing with the modified Bass method. After two weeks of SRP, Prescribe 50,000 IU of vitamin D weekly.

Category

Treatment - Drugs

3

Description

Control group: Scaling & Root Planning of the whole mouth and then hygiene training is done similarly by flossing and brushing with the modified Bass method. No medication is prescribed for this group as a control group

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Qom Dental School-Periodontics department

Full name of responsible person

Dr. Leila Khodadadifard

Street address

Qom School of Dentistry, Lavasani St.

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3713649373

Phone

+98 25 3770 0095

Email

l.khodadadifard@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Dr. Ehsan Sharifipour

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No 83, Jihad Daneshgahi Alley, Shahid Lotfi Niasar (Alley No. 4), Safashahr St.

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research@mail.muq.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ghoum University of Medical Sciences

Proportion provided by this source

80

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

Ghoum University of Medical Sciences

Full name of responsible person

Fateme Abedini

Position

Dentistry student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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39367-37136

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dentistryabedini74@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Dr. Leila Khodadadifard

Position

Periodontist, Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Fateme Abedini

Position

Dentistry student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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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

All data can potentially be shared after unidentified individuals

When the data will become available and for how long

access the data 6month after the result are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

People working on patients with periodontitis or vitamin D deficiency

From where data/document is obtainable

Applicants can apply via the following e-mail to receive the required documents or data

dentistryabedini74@gmail.com

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

Email to the project presenter-Request from the Vice Chancellor for Research-If positive, provide information to the applicant

Comments