Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation the effect of vitamin D3 in improvement clinical parameters of patients with chronic periodontitis-clinical trial

Protocol summary

Study aim
Investigating the effect of vitamin 3D on the average clinical indicators of chronic periodontitis in the group consuming vitamin D3 and the placebo group

Design
A controlled, parallel-group, double-blind, randomized, phase 4 clinical trial on 32 patients. Random allocation software was used for randomization.

Settings and conduct
This study is a double-blind randomized clinical trial study after the proposal was approved by the Research Council of the Yazd School of Dentistry with a sample size of 32 people in the age group of 30 to 45 years with periodontitis stage 1 and 2 and vitamin D3 deficiency from patients referred to Yazd Faculty of Dentistry is done. The samples will be divided into two experimental and control groups. The experimental group will be given oral vitamin 3D supplement and the control group will be given placebo. After three months, the indicators of bleeding after probing (BOP), pocket depth (PD), clinical adhesion loss (CAL) will be compared in two groups.

Participants/Inclusion and exclusion criteria
Entry criteria: female should be healthy, between 30 and 45 years old, have at least 20 teeth and levels below 30 ng/ml. Inclusion criteria: no recent antibiotic treatment, vitamin D supplements, corticosteroids or immunosuppressive drugs, aspirin use, NSAID use, bisphosphonates or hormone therapy, patients who were in menopause, patients who were pregnant, patient with a history of infective endocarditis, congenital problem or acquired heart defects, immunodeficiency, history of diabetes, calcium deficiency, bone diseases or other systemic conditions that may affect the periodontium and the treatment protocol

Intervention groups
Intervention group: the group receiving vitamin d3 soft gel 4000 IU. Control group: the group receiving placebo soft gel without active ingredient.

Main outcome variables
clinical attachment loss; probing depth; bleeding on probing

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221212056786N3**
Registration date: **2023-11-05, 1402/08/14**
Registration timing: **prospective**

Last update: **2023-11-05, 1402/08/14**
Update count: **0**

Registration date
2023-11-05, 1402/08/14

Registrant information

Name
Seyed mohammad Arab farashahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3621 2222

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-11, 1402/09/20

Expected recruitment end date
2024-02-09, 1402/11/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation the effect of vitamin D3 in improvement clinical parameters of patients with chronic periodontitis-clinical trial

Public title
Evaluation the effect of vitamin D3 in improvement clinical parameters of patients with chronic periodontitis-clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
female Has at least 20 teeth Blood vitamin D levels below 30 ng/ml (normal level is ≥ 30 ng/ml). Healthy Between 30 and 45 years

Exclusion criteria:
Recent antibiotic therapy Taking vitamin D supplements Use of corticosteroids or immunosuppressive drugs Taking aspirin tablets NSAID use Taking bisphosphonates or hormone therapy Patients who were in menopause or pregnancy Bone diseases Patient with history of infective endocarditis, congenital problem or acquired heart defects Immunodeficiency History of diabetes Calcium deficiency Other systemic conditions that may affect the periodontium and the treatment protocol

Age
From **30 years** old to **45 years** old

Gender
Female

Phase
4

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients are placed in two groups using Random Allocation software version 1.0 under Windows and stratified in a simple random manner based on age so that the two groups are the same in terms of age.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the study participants and the researcher will be unaware of the division of patients into experimental and control groups, and only a third person outside the study will be aware of the division method. (double-blinding) Vitamin 3D supplement and placebo will be provided to patients in the same containers. (so that the contents of the containers are not visible from the outside)

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
کمیته اخلاق دانشکده دندان پزشکی _ دانشگاه علوم پزشکی شهید صدوقی یزد

Street address
Yazd-Imam Street-Beginning of Daheh Fajr Boulevard-Shahid Sadoughi Dental School, Yazd

City
yazd

Province
Yazd

Postal code
8914881167

Approval date
2023-03-13, 1401/12/22

Ethics committee reference number
IR.SSU.DENTISTRY.REC.1401.095

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
clinical attachment loss

Timepoint
At the beginning of the study and 12 weeks after the start of vitamin D intake

Method of measurement
Williams periodontal probe

Secondary outcomes

1

Description
probing depth

Timepoint

At the beginning of the study and 12 weeks after the start of vitamin D intake

Method of measurement

Williams periodontal probe

2

Description

Bleeding on probing

Timepoint

At the beginning of the study and 12 weeks after the start of vitamin D intake

Method of measurement

Williams periodontal probe

Intervention groups

1

Description

Intervention group: The ingredient used is vitamin D3 4000 soft gel in yellow color. Two 4000 IU vitamin D3 oral supplement capsules (Dana Pharmaceutical Company product) daily, one in the morning and one at night, will be given to the patients of this group every day (seven days a week) for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: They will receive the placebo in the form of a soft gel without the active ingredient, which is similar in size and color to vitamin D3. The patient should take one pill in the morning and one pill at night, every day (seven days a week) for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Faculty of Dentistry, Yazd

Full name of responsible person

seyed mohammad arab farashahi

Street address

Yazd-Imam Street-Beginning of Daheh Fajr Boulevard-Shahid Sadoughi Dental School, Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

mina zamani

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person
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Associate professor

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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
Undecided - It is not yet known if there will be 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