Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of non-surgical periodontal therapy on serum 25-hydroxyvitamin D level in postmenopausal women with chronic periodontitis.

Protocol summary

Study aim

The aim of this study is to measure the serum 25-hydroxyvitamin-D concentration changes of postmenopausal women with chronic periodontitis before and after non-surgical periodontal treatment and to evaluate the correlation between those changes and clinical periodontal parameters.

Design

Two arm, parallel, not blinded trial (postoperative care and outcome assessment). Randomization was computerized with concealed randomization sequence carried out at an external site.

Settings and conduct

People with inclusion criteria who refer to Tabriz University periodontics ward, enter to study after giving informed consent.

Participants/Inclusion and exclusion criteria

inclusion criteria:This study is performed on postmenopausal women who are at least 50 years old, and a year, at least, is passed since the menopause has begun;PD greater than or equal to 5mm; generalized attachment loss greater than or equal to 5 mm(more than 30% of the sites are involved); presence of radiographic evidence of alveolar bone loss. Exclusion criteria: 1) a history of NSAIDs or antimicrobial drugs intake within a 6 month period before the study;2) history of any periodontal treatment within a 6 month period before the study;3) presence of any systemic disease and infection other than chronic periodontitis;4) presence of aggressive periodontitis;5) presence of systemic diseases that interfere with bone metabolism and immune system, such as kidney failure, diabetes and the presence of bone lesions. 6)use of mouthwashes or vitamin supplements within the previous 3 months

Intervention groups

Intervention: Patients in the chronic periodontitis group received nonsurgical periodontal therapy, including oral hygiene instructions(flossing & brushing with Bass technique), and scaling and root planing in one 1hour session.then, 0.12 % chlorhexidine mouthwash(Cosmodent Co.,Gingival KIN,spain) was prescribed for 14 days(15ml for 30seconds twice a day).

Main outcome variables

main outcome variables: serum 25-hydroxyvitamin D is a primary variable and clinical periodontal parameters are secondary variables include serum 25-hydroxyvitamin D levels(by venus blood sample) and clinical periodontal parameters(Pocket depth, Clinical attachment loss, Bleeding on probing, Gingival index, Plaque index by periodontal probe) which are recorded at baseline and 3 months later.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110726007128N10**
Registration date: **2018-01-27, 1396/11/07**
Registration timing: **retrospective**

Last update: **2018-01-27, 1396/11/07**
Update count: **0**

Registration date

2018-01-27, 1396/11/07

Registrant information

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Adileh Shirmohammadi
Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2018-01-02, 1396/10/12
Expected recruitment end date
2018-01-03, 1396/10/13
Actual recruitment start date
2018-01-03, 1396/10/13
Actual recruitment end date
2018-01-04, 1396/10/14
Trial completion date
empty

Scientific title
Effect of non-surgical periodontal therapy on serum 25-hydroxyvitamin D level in postmenopausal women with chronic periodontitis.

Public title
Effect of non-surgical periodontal therapy on serum level of 25-hydroxyvitamin D and clinical parameters in patients with periodontal disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
postmenopausal women who are at least 50 years old, and at least one year is passed since the menopausal beginning. Pocket depth is greater than or equal to 5mm generalized attachment loss greater than or equal to 5 mm (more than 30% of the sites are involved) radiographic evidence of alveolar bone loss
Exclusion criteria:
The history of NSAIDs or antimicrobial drugs intake within previous 6 months The history of any periodontal treatment within previous 6 months The presence of any systemic disease and infection The presence of aggressive periodontitis use of mouthwashes or vitamin supplements within the previous 3 months
Age
From **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Actual sample size reached: **27**
Randomization (investigator's opinion)
N/A
Randomization description
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 Tabriz Univercity of Medical Sciences
Street address
Tabriz University of Medical Siences, Golgasht St., Daneshgah St., Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5371733671
Approval date
2018-01-01, 1396/10/11
Ethics committee reference number
IR.TBZMED.REC.1396.919

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-hydroxyvitamin D
Timepoint
Base line-3month
Method of measurement
laboratory test

Secondary outcomes

1

Description
Clinical parameters of periodontium
Timepoint
Base line-3month
Method of measurement
periodontal probing

Intervention groups

1

Description
Intervention group: chronic periodontitis : Patients in the chronic periodontitis group received nonsurgical periodontal therapy, including oral hygiene instructions(flossing & brushing with Bass technique), and scaling and root planing in one 1hour session.then, 0.12 % chlorhexidine mouthwash(Cosmodent Co.,Gingival KIN,spain) was prescribed for 14 days(15ml for 30seconds twice a day).

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Dentistry faculty of Tabriz, Periodontics ward

Full name of responsible person
Dr. Adileh Shirmohamadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research of Tabriz 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
Vice chancellor for research of Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Sanaz Mohammadi

Position
دانشجوی دندانپزشکی

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Position
Periodontist/ Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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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