Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluating the effect of vitamin D3 supplementation on chronic osteomyelitis treatment and on sleep quality, anxiety and depression in patients with chronic osteomyelitis

Protocol summary

Summary

The aim of this placebo controlled double blind randomized clinical trial will be to evaluate the effect of vitamin D3 supplementation on chronic osteomyelitis treatment and on sleep quality, anxiety and depression in patients with chronic osteomyelitis. Inclusion criterion is patients with chronic osteomyelitis ranged in age from 16 to 55 years old. The main exclusion criteria are concurrent other vitamin D supplements use during the study and use of immunosuppressants . A total of 50 patients will be recruited from clinic. These patients will be divided into two groups (intervention and placebo), each have 25 patients, using block randomization. After signing informed consent form by patients, vitamin D3 will be administered 200000 units at baseline and 100000 units after one, two, three, four and five months in intervention group and patients will take placebo with the same dose and frequency in placebo group. Depression, anxiety, and sleep quality will be evaluated using self-reported questionnaires at baseline, after 3 and 6 months. Clinical presentations, ESR, and CRP will be also evaluated at baseline and after 2 weeks, one, two, three, four, five and six months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201609026026N4**
Registration date: **2017-04-10, 1396/01/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-10, 1396/01/21

Registrant information

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Fatemeh Dabaghzadeh
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Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2016-09-28, 1395/07/07

Expected recruitment end date

2018-09-29, 1397/07/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of vitamin D3 supplementation on chronic osteomyelitis treatment and on sleep quality, anxiety and depression in patients with chronic osteomyelitis

Public title

Evaluating the effect of vitamin D3 supplementation on bone infection treatment and on sleep quality, anxiety and depression in patients with bone infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with chronic osteomyelitis in the 16-55 age range Exclusion criteria: use of other vitamin D supplements; use of immunosuppressants; history of hypercalcemia or nephrolithiasis; sarcoidosis; kidney disorders requiring dialysis or polycystic kidney disease; cirrhosis; cancer; baseline plasma calcium (corrected for plasma albumin concentration) greater than 10.4 mg/dL or less than 8.4 mg/dL

Age
From **16 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kerman University of Medical Sciences

Street address
Tahmasb abad Ave

City
Kerman

Postal code

Approval date
2017-03-12, 1395/12/22

Ethics committee reference number
IR.KMU.REC.1395.786

Health conditions studied

1

Description of health condition studied
Chronic osteomyelitis

ICD-10 code
A49.0

ICD-10 code description
Staphylococcal infection, unspecified site

Primary outcomes

1

Description
ESR

Timepoint
At baseline, after 2 weeks and after 1, 2,3,4, 5 and 6 months

Method of measurement
Blood test

2

Description
CRP

Timepoint
At baseline, after 2 weeks and after 1, 2,3,4, 5 and 6 months

Method of measurement
Blood test

3

Description
Clinical presentations

Timepoint
At baseline, after 2 weeks and after 1, 2,3,4, 5 and 6 months

Method of measurement
Physical examination

Secondary outcomes

1

Description
Mental disorders

Timepoint
At baseline, after 3 and 6 months

Method of measurement
Questionnaires

Intervention groups

1

Description
Intervention: Four vitamin D3 pearls (50000 IU) at baseline and two vitamin D3 pearls (50000 IU) after 1, 2, 3, 4, and 5 months

Category
Treatment - Drugs

2

Description
Control: Four placebo pearls at baseline and two placebo pearls after 1, 2, 3, 4, and 5 months

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat clinic
Full name of responsible person
Fatemeh Dabaghzadeh
Street address
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman Univesity of Medical Sciences
Full name of responsible person
Miz. Hasani
Street address
Tahmasb abad Ave
City
Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman Univesity of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code

empty

Data Dictionary

empty