Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of the effect of alkaline drinking water on bone density in menopausal women with osteoporosis

Protocol summary

Study aim
Determining the effect of alkaline drinking water on bone density in menopausal women with osteoporosis
Design
Clinical trial with control group, simple individual randomized, double blind, on 100 patients, for 3 months. Evaluation will be done at the first visit and 3 months later for bone densitometry.
Settings and conduct
The studied group was selected from patients referred to the clinics of Shahrekord University of Medical Sciences
Participants/Inclusion and exclusion criteria
Inclusion Criteria: Postmenopausal women who at least 12 months past after amenorrhea without association with pregnancy, breast-feeding or other hormonal disorders; prone to osreoprosis with T score of less than 2.5 in bone density measurement. Exclusion criteria: Gastrointestinal absorption disorder; patients with thyroid diseases; Kidney and liver diseases
Intervention groups
The intervention group received combined calcium and vitamin D (Ca-D3) supplement with loading dose of 400 International Unit(IU) of cholecalciferol and 500 mg calcium once daily, also they consumed 1.5 Litter/day alkaline drinking water (pH = 8.6 ± 0.3) (23) and Osteofos tablet (70 mg) once a week. Control group received Ca-D3 tablet daily and Osteofos tablet (70 mg/kg) once a week.
Main outcome variables
Bone Density

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170929036477N3**
Registration date: **2021-03-09, 1399/12/19**
Registration timing: **retrospective**
Last update: **2021-03-09, 1399/12/19**
Update count: **0**
Registration date
2021-03-09, 1399/12/19

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 36688487
Email address
siavashfazelian@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-05-17, 1396/02/27
Expected recruitment end date
2018-04-09, 1397/01/20
Actual recruitment start date
2018-01-10, 1396/10/20
Actual recruitment end date
2018-08-28, 1397/06/06
Trial completion date
2018-12-01, 1397/09/10

Scientific title
Evaluation of the effect of alkaline drinking water on bone density in menopausal women with osteoporosis

Public title
Effect of alkaline water on bone health
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Postmenopausal women Having at least 12 months of menstruation pause and osteoporosis Prone to

osteoporesis with T score of less than 2.5 in bone density measurement

Exclusion criteria:

Pregnancy Breastfeeding Smoking Drinking alcohol Other hormonal disorders Use hormones or drugs with negative or positive effect on bone metabolism (such as, estrogens and bisphosphates) in the past year Involuntary participating in the study Allergy to drugs Certain complications such as hallucinations, confusion and numbness Nausea, vomiting, Restlessness Seizure Disorders of intestinal absorption Thyroid, kidney or liver disorders

Age

From **30 years** old to **75 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible subject be selected with convenience sampling and be randomly assigned into 2 groups of 50 subjects with block sizes of 3 and 6 with proportion 1:1:1. A person from research team not involved in the recruitment and assigning participants generate allocation sequence using a computerized program. Opaque sealed sequentially numbered envelops be used for allocation concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

All participants and investigators were blinded to type of intervention. Drugs and placebo were similar in the color and size and they were presented in dark bottles (A, B) coded by a subject who was not involved in any procedures of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University Of Medical Sciences

Street address

Shahrekord University Of Medical Sciences, Rahmatieh, Shahrekord

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۵۷۱۳۴۷۱

Approval date

2017-07-08, 1396/04/17

Ethics committee reference number

IR.SKUMS.REC.1396.174

Health conditions studied

1

Description of health condition studied

osteoporosis

ICD-10 code

M80

ICD-10 code description

Osteoporosis with current pathological fracture

Primary outcomes

1

Description

T score

Timepoint

At the beginning of the study and 3 months later

Method of measurement

Bone densitometry

Secondary outcomes

1

Description

Bone density

Timepoint

At first visit and then 3 months after start of intevention

Method of measurement

Bone Densitometry

Intervention groups

1

Description

Intervention group: combined calcium and vitamin D (Ca-D3) supplement with loading dose of 400 International Unit(IU) of cholecalciferol and 500 mg calcium per day once daily,(23) and Osteofos tablet (70 mg) once a week also they consumed 1.5 Litter/day alkaline drinking water (pH = 8.6 ± 0.3)

Category

Treatment - Drugs

2

Description
Control group received Ca-D3 tablet daily and Osteofos tablet (70 mg/kg) once a week.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Subspecialty Clinic
Full name of responsible person
Dr Morteza Dehghan
Street address
Shariati Boulevard
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
۸۸۱۵۷۱۳۴۷۱
Phone
+98 38 3333 0061
Email
Siavashfazelian@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr Morteza Dehghan
Street address
Kashani Blvd
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
۸۸۱۵۷۱۳۴۷۱
Phone
+98 38 3333 0061
Email
Siavashfazelian@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahrekord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr Morteza Dehghan
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
Street address
Kashani Blvd
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
۸۸۱۵۷۱۳۴۷۱
Phone
+98 38 3333 0061
Email
siavashfazelian@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr Morteza Dehghan
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Phone
+98 38 3333 0061
Email
siavashfazelian@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Dr Morteza Dehghan

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
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Phone
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Email
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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
After ensuring that the participants are not identifiable, all potential data could be shared.

When the data will become available and for how long
6 months after article publication

To whom data/document is available
Researchers that are working at Shahre-kord University of Medical Sciences.

Under which criteria data/document could be used
In condition in which the priority of research innovation is not threatened.

From where data/document is obtainable
Sending the request to the corresponding author via email.

What processes are involved for a request to access data/document
The request is reviewed by the corresponding author and the decision will be made within 2 weeks of after receiving the request

Comments