Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of the effects of vitamin D fortified oil and vitamin D supplement in improving vitamin D status and bone turnover factors among 18-30 healthy persons.

Protocol summary

Study aim

Comparing the effect of vitamin D supplement and vitamin D enriched oil on serum vitamin D status and bone turnover indices in healthy individuals aged 18 to 30 years

Design

Clinical trial with three parallel intervention groups including 33 participants. Double-blinded, randomized using random digits table

Settings and conduct

Following inviting people to the study, eligible volunteers will be entered the study. Participants will be grouped in A, B and C groups. The study will be double blinded. After the initial blood sampling, participants will use pills and oil for 3 months. At the end of the third month, blood sampling will be done again and 25(OH)D, PTH, BAP and CTX-I will be measured and compared with parameters of the final and first blood samples.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 30-18 years old Exclusion criteria: Diseases which influence the metabolism of P, Ca and vitamin D Treatment for osteoporosis in the last 6 months Using Glucocorticoids Pregnancy or lactating Participating in other studies in the last 6 months

Intervention groups

Group 1: A supplement tablet containing 1000 IU of vitamin D per day + 25 g of ordinary canola oil, group 2: a placebo tablet + 25 grams of vitamin D enriched canola oil containing 1000 IU of vitamin D per day; group 3: a placebo tablet + 25 grams of ordinary canola oil per day

Main outcome variables

25-hydroxy vitamin D, PTH, bone specific alkalin phosphatase (BAP), CTX-I

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180708040401N1**
Registration date: **2018-10-04, 1397/07/12**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-04, 1397/07/12**
Update count: **0**

Registration date

2018-10-04, 1397/07/12

Registrant information

Name

Negar Ghasemifard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3725 1006

Email address

nghasemifard@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effects of vitamin D fortified oil and vitamin D supplement in improving vitamin D status and bone turnover factors among 18-30 healthy persons.

Public title
Fortification and supplementation effect on vitamin D levels

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
18-30 years old The absence of diseases which influence the metabolism of Ca, P and vitamin D such as thyroid and parathyroid disorders, chronic kidney disease, osteoporosis, or bone fractures caused by osteoporosis, during the past year The absence of cardiovascular disease, diabetes, chronic digestive diseases, hepatitis and cancer No medical treatment for osteoporosis or other bone diseases in the last 6 months, such as taking Bisphosphonates, Raloxifene, Teriparatide and Denosambe Not using Glucocorticoids Not using nutritional supplements No pregnancy and lactation Not participating in other studies in the last 6 months

Exclusion criteria:
The presence of diseases affecting the metabolism of phosphorus, calcium and vitamin D The presence of cardiovascular disease, diabetes, chronic diseases of the digestive tract, hepatitis and cancer Medical treatment for osteoporosis or other bone diseases in the last 6 months Treatment with glucocorticoids Using nutritional supplements Pregnancy and lactating Participating in other studies in the last 6 months

Age
From **18 years** old to **30 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **99**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization by random digits table: participants are numbered from 1 to 99, then a row and a column of the random digits table are chosen randomly, the place of intersection of the row and the column is considered as the beginning point. We move our hand continuously on the table, the first number which the last two digits are the number of one of participants, is placed in the first group, the second number in the second group, the third number in the third group; and we go on to dedicate 33 participants in each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Someone who is not participating in the study, grouped oils and pills, then delivered them to the researcher so all individuals involved in the study are blind. Placebo pills are quite similar to vitamin D pills (produced by the same company). Fortified oil are also completely the same as unfortified oil in terms of color and packaging.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Science

Street address
Central Building of Shiraz University of Medical Sciences-opposite Palestin Street-Zand Avenue

City
Shiraz

Province
Fars

Postal code
7134814336

Approval date
2017-11-05, 1396/08/14

Ethics committee reference number
IR.SUMS.REC.1396.124

Health conditions studied

1

Description of health condition studied
Healthy people

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
25-hydroxy vitamin D

Timepoint
Beginning of the study (before starting intervention), at the end of the study (after the end of intervention)

Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

2

Description
Parathyroid hormone
Timepoint
Beginning of the study (before starting intervention), at the end of the study (after the end of intervention)
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

3

Description
Bone specific alkalin phosphatase
Timepoint
Beginning of the study (before starting intervention), at the end of the study (after the end of intervention)
Method of measurement
Spectophotometric assay

4

Description
collagen type 1 cross-linked C-telopeptide I(CTX-I)
Timepoint
Beginning of the study (before starting intervention), at the end of the study (after the end of intervention)
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: a supplement tablet containing 1000 IU vitamin D per day + 25 gram ordinary canola oil
Category
Treatment - Drugs

2

Description
Intervention group: a placebo tablet + 25 gram canola oil enriched by 1000 IU vitamin D per day
Category
Treatment - Drugs

3

Description
Control group: a placebo tablet + 25 gram ordinary canola oil
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza clinic
Full name of responsible person
Ali Jangjo
Street address
Emam Reza specialized clinic, next to blood transfusion center, Namazi square
City
Shiraz
Province
Fars
Postal code
71348714737
Phone
+98 71 3212 7001
Email
emamreza@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Research and Technology Deputy of Shiraz University of Medical Sciences
Street address
Research and technology deputy-7 floor-central building of Shiraz university of medical science-opposite Palestin Street-Zand Avenue
City
Shiraz
Province
Fars
Postal code
71348-14336
Phone
+98 71 3235 7282
Fax
+98 71 3212 2430
Email
vcrdep@sums.ac.ir
Grant name
Research grant
Grant code / Reference number
SG-96-14
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Shiva Faghih

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Nutrition and food science faculty, opposite of Bargh club, Razi Blvd

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71536-75541

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Shiva Faghih

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Negar Ghasemifard

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

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Fax

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Email

nghasemifard@yahoo.com

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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data file, information related to main variable will be shared. The study protocol is fully be shared. I will share the informed consent forms.

When the data will become available and for how long

first accessibility after submitting the article.

To whom data/document is available

Data will be available to academic researchers.

Under which criteria data/document could be used

I have not decided yet.

From where data/document is obtainable

Doctor Shiva Faghih: shivafaghih@gamail.com

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

After posting the email, his request is checked and, if the criteria are met, the data will be sent to him.

Comments