Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of Satisfaction and Short-term Side effect after OsteoCalVitFort Practice in population whom use Calcium Supplement

Protocol summary

Summary

Nutritional studies have shown that many people do not get enough calcium and maintain bone mass are tailored to the needs of growth and development . The presence of vitamin D for proper absorption of calcium is necessary anymore. But calcium supplementation are creating digestive disorders and other side effect . Seems to OsteoCalVit Fort because of calcium carbonate salt, due to create fewer gastrointestinal side effects in consumers. The aim of this study is to evaluate the short-term side effects and satisfaction of the consumer of OsteoCalVit Fort compared with calcium prior to any other business deals. The present study is phase 4, single- arm,after entering care. Inclusion criteria: patients aged 45 to 70 years who used calcium supplements, good health, according to a biochemical level , the willingness to sign a written informed consent to participate in this trial, which is to announce and The exclusion criteria were People biochemical tests may not be appropriate, in certain diseases such as cancer, kidney stones or have any drug allergy, people who are willing to enter the study.By 2 times capsule of OsteoCalVit Fort for one month usage, the evaluation of the short-term side effects and satisfaction of the consumer in comparison with other marketing Calcium, will be considered .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312031414N30**
Registration date: **2014-02-24, 1392/12/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-02-24, 1392/12/05

Registrant information

Name
Bagher Larijani
Name of organization / entity
Endocrinology & Metabolism Research Center, Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 21 8822 0037
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emrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

pharmedshayan pharmaceutical

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-03-01, 1392/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Satisfaction and Short-term Side effect after OsteoCalVitFort Practice in population whom use Calcium Supplement

Public title

Evaluation of Satisfaction and Short-term Side effect after OsteoCalVitFort Practice

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Age between 45 to 70 years old who received Calcium supplement; In good health, as determined by the principal investigator based on medical history and physical examination; Clinical laboratory evaluations within the reference range for the test laboratory; Ability to comprehend and willingness to sign the Informed Consent Form for this study. Exclusion criteria: Clinically complicated biochemical tests; Any diagnosed malignancy; Any drug hypersensitivity; History of kidney stone; hyperparathyroidism or sarcoidosis; unwilling to participation.

Age
From **45 years** old to **75 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Endocrinology Metabolism Research Institute

Street address
5th floor, Shariati Hospital, Jalla Ale Ahmad St

City
Tehran

Postal code

Approval date
2014-01-08, 1392/10/18

Ethics committee reference number
EC-00302

Health conditions studied

1

Description of health condition studied
side effect of Calcium vitamin D

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Side Effects

Timepoint
befor intervention and 1 month after intervention

Method of measurement
Questionnarie

Secondary outcomes

1

Description
Satisfaction

Timepoint
1 month Aftere the intervention

Method of measurement
Qusetionnarie

Intervention groups

1

Description
phase 4, single arm , one-month study, after entering care, 2 times OsteoCalVit Fort use for one month.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Endocrinolog and Metabolism Research Center

Full name of responsible person
Bagher Larijani

Street address
5th floor, Shariati Hospital, Jallale Ale Ahmad St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
pharmedshayan pharmaceutical

Full name of responsible person
Dr Hosein Gharib

Street address
No 18, 18th Allay, Kordestan

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

pharmedshayan pharmaceutical

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Endocrinolog and Metabolism Research Institute

Full name of responsible person

Bagher Larijani

Position

Endocrinologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Chronic Disease Research Center

Full name of responsible person

Maryam Sanaei

Position

MSc of microbiology/ clinical trial coordinator

Other areas of specialty/work

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No 111, 2 Floor, 19th Allay, North Karegar,Amir Abad.

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sanaeimaryam@yahoo.com

Web page address

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