

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the Efficacy of Nano Calcium and Marketed Calcium Supplements in Improving Bone Health in Osteopenia Population : A Randomized Clinical Trial

Protocol summary

Summary

Current study will compare the effectiveness of AceNano Calcium and Carbonate Calcium in improving Improving Bone Health in Osteopenia Population. The purpose of this supplement to prevent osteoporosis in people with osteoporosis and T-score between minus one and minus two and a half more. This study is a interventional, phase III, randomized, two- arm parallel group. In this clinical trial, 40 osteopenic participate which are divided into two groups: 1- 20 people AceNano Calcium usage and 2-20 use Carbonate Calcium as a calcium supplementation. Inclusion criteria: diagnosis of osteopenia based on BMD results the T-Score between -1 and -2.5, both genders, aged between 45 and 70 years. Exclusion Criteria: any disorder that impairs mental and relationship disorders questionnaire or other words that researchers can study verbal communication to interact with the person, pregnant or nursing women, a disease affecting bone mineral density (acute or chronic renal failure, liver failure, any type of cancer, chronic diarrhea (more than two weeks). Current study will measure blood Calcium bone, marker turnover, Osteocalcin and bone alkaline phosphatase blood.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201401131414N31**
Registration date: **2014-02-22, 1392/12/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-02-22, 1392/12/03

Registrant information

Name

Bagher Larijani

Name of organization / entity

Endocrinology & Metabolism Research Center, Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8822 0037

Email address

emrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Neutrino Noavarane Nano

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Efficacy of Nano Calcium and Marketed Calcium Supplements in Improving Bone Health in Osteopenia Population : A Randomized Clinical Trial

Public title

The efficacy of Nano calcium in improving bone health

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion: Osteopenia with T-Score -1 and -2.5; both male

and female; Age between 45 to 70 Exclusion: Presence of any systemic or chronic illness such as: Chronic hepatic diseases, Clinically complicated pulmonary, cardiac, hematologic, gastrointestinal, Serious psychological problems such as severe anxiety or depression, Any diagnosed malignancy, A history of active inflammatory illness, Breast feeding, pregnancy or intention to become pregnant during the study period (female patients), Any drug hypersensitivity, Radiotherapy, Chemotherapy or any immunosuppressive drug use, Use of another investigational agent within 6 months of the screening visit, History of kidney stone, hyperparathyroidism or sarcoidosis.

Age

From **45 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

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 Endocrinology Metabolism
Research Institute

Street address

5th floor, Shariati Hospital, Jalla Ale Ahmad St

City

Tehran

Postal code**Approval date**

2014-01-11, 1392/10/21

Ethics committee reference number

EC-00329

Health conditions studied**1****Description of health condition studied**

Osteopenia

ICD-10 code

M85.9

ICD-10 code description

Disorders of Bone Density and Structure, Unspecified

Primary outcomes**1****Description**

Osteocalcin

Timepoint

befor and after intervention

Method of measurement

photometry

Secondary outcomes**1****Description**

serum level of Vitamin D

Timepoint

before and after intervention

Method of measurement

ELISA

2**Description**

PTH

Timepoint

before and after intervention

Method of measurement

ELISA

3**Description**

serum Alkalinephosphatase

Timepoint

before and after intervention

Method of measurement

photometry

4**Description**

Alb

Timepoint

before and after intervention

Method of measurement

photometry

5**Description**

Protein

Timepoint

before and after intervention
Method of measurement
photometry

6

Description
Cr
Timepoint
before and after intervention
Method of measurement
photometry

7

Description
Calcium
Timepoint
before and after intervention
Method of measurement
photometry

8

Description
Phosphate
Timepoint
before and after intervention
Method of measurement
photometry

Intervention groups

1

Description
Marketing Carbonate Calcium with 500 mg, 2 times daily
, 3-month use .
Category
Treatment - Drugs

2

Description
AceNano Calcium with 72 mg Carbonate Calcium
Elemental, 3 times daily, 3-month use
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinolog and Metabolism Research Institute
Full name of responsible person
Dr. AbbasAli Keshtkar
Street address
5 th floor, Shariati Hospital,Jallale Ale Ahmad St
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Neutrino Noavarane Nano
Full name of responsible person
Ghorbankhani
Street address
No 20,9th Floor, Goldis Tower , 2nd Sadeghieh
Sq,Tehran.
City
Tehran
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Neutrino Noavarane Nano
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
Dr.Bagher Larijani
Position
Endocrinologist
Other areas of specialty/work
Street address
5th floor, Shariati hospital, Jallale Ale Ahmad
City
Tehran
Postal code
Phone
+98 21 8822 0053
Fax
+98 88220052
Email
emrc@tums.ac.ir
Web page address

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**Street address**

No111,19th Allay, North Karegar, Amir Abad

City

Tehran

Postal code**Phone**

+98 21 8835 4309

Fax**Email**

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