Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Assessment the effect of vitamin D supplementation on plasma vitamin D levels, inflammatory and antioxidant biomarkers and factors associated with cell proliferation, differentiation, damage and appopotosis in breast cancer survivor

Protocol summary

Summary

This is an interventional study which will assess the effect of vitamin D supplementation on plasma vitamin D levels, inflammatory and antioxidant biomarkers and factors associated with cell proliferation, differentiation, damage and apoptosis in breast cancer survivor based on polymorphisms in vitamin D receptor (VDR) gene. Present study will be conducted on breast cancer survivor referring to Shohadaye Tajrish hospital and its associated clinics. One hundred sixty-five breast cancer survivor will receive 4000 IU of vitamin D3 daily for 12 weeks. VDR Fok1, Apa I, TaqI, BsmI and Cdx-2 genotypes will be determined at the end of the study and responses to vitamin D supplement e.g. inflammatory, antioxidant, cell proliferation, differentiation, damage and apoptosis will be compared between three subgroups of each VDR polymorphisms.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017091736244N1**
Registration date: **2017-11-10, 1396/08/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-11-10, 1396/08/19

Registrant information

Name

Elham Kazemian

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

1) Vice chancellor for research, Faculty of Nutrition Sciences and Food Technology and National Nutrition and Food Technology Research Institute, Shahid Beheshti University of Medical Sciences, Tehran, Iran2) Vice chancellor for research, Cancer Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran3) Vice chancellor for research, Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences, Tehran, Iran

Expected recruitment start date

2016-02-02, 1394/11/13

Expected recruitment end date

2016-03-08, 1394/12/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of vitamin D supplementation on plasma vitamin D levels, inflammatory and antioxidant biomarkers and factors associated with cell proliferation, differentiation, damage and appopotosis in breast cancer survivor

Public title
Vitamin D supplementation and breast cancer prevention
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Patients with breast cancer including invasive or in situ carcinoma whose cancer was approved through pathological examination; Women aged 25-65 years; BMI between 25 to 35 kg/m2; not using 1000 IU daily or 50000 IU weekly or 300000 intramuscular injection of vitamin D supplement for at least 4 months before the study; not using dietary, herbal or omega-3 supplements during the intervention period; Patients were diagnosed with breast cancer at least 6 months prior the study and treatment protocols including surgery, radiotherapy and chemotherapy were completed. Exclusion criteria: History of malabsorption syndrome, calcium metabolism disorder, gastrointestinal, renal, inflammatory (sarcoidosis, etc.) and other endocrinological diseases; Treatment for weight reduction; high levels of plasma vitamin D
Age
From **25 years** old to **65 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **165**
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 faculty of Nutrition Sciences and Food Technology and National Nutrition and Foo
Street address
No 7, Hafezi st. Farahzadi Blvd., Sharake Qods
City
Tehran
Postal code
Approval date
2016-01-21, 1394/11/01
Ethics committee reference number
IR.SBMU.NNFTRI.REC.1395.62

Health conditions studied

1

Description of health condition studied
Breast Cancer Survivour
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
plasma vitamin D level
Timepoint
Baseline and post- intervention
Method of measurement
ELISA

Secondary outcomes

1

Description
Oxidative stress biomarkers including Malondialdehyde (MDA), Total Antioxidant Capacity (TAC), Superoxide dismutase (SOD)
Timepoint
Baseline and post- intervention
Method of measurement
ELISA and colorometic method

2

Description
Inflammatory biomarkers including high-sensitivity C-reactive protein (hs-CRP), Tumor necrosis factor alpha (TNFα), Interleukin 6 (IL-6), β-Interferon (IFN-β)
Timepoint
Baseline and post- intervention
Method of measurement
ELISA

3

Description
Biomarkers associated with cell proliferation, differentiation, damage and apoptosis including Matrix metallopeptidase 9 (MMP-9), Plasminogen activator inhibitor-1 (PAI-1), 8-hydroxy-2'-deoxyguanosine (8-OHdG), E-cadherin, B-cell lymphoma2 (Bcl-2), Intercellular adhesion molecule 1 (ICAM-1), Vascular cell adhesion molecule 1 (VCAM-1)
Timepoint
Baseline and post- intervention
Method of measurement
ELISA

4

Description
Anthropometric indicators including Weight, Height, Body Mass Index (BMI), Waist Circumferences, Hip Circumferences, Body Composition
Timepoint
Baseline and post- intervention
Method of measurement
Digital scale,stadiometer, measuring tape

5

Description
Metabolic profiles including low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol, total cholesterol (TC), triglyceride (TG), Aspartate Aminotransferase (SGOT), glutamate-pyruvate transaminase (SGPT), Urea, Creatinine
Timepoint
Baseline and post- intervention
Method of measurement
Colorometic method

Intervention groups

1

Description
Supplement therapy with daily dose of 4000 IU cholecalciferol for 12 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Cancer Research Center, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Street address
Shohadaye Tajrrish Hospital, Tajrish Sq.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Cancer Research Center, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Seyed Hossein Davoodi
Street address
Shohadaye Tajrrish Hospital, Tajrish Sq.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Cancer Research Center, Shahid Beheshti University of Medical Sciences
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Endocrine Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of
Full name of responsible person
Dr. Atieh Amouzegar
Street address
Araabi St., Yaman Ave, Chamran High Way
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Endocrine Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of
Proportion provided by this source
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

3

Sponsor
Name of organization / entity
Faculty of Nutrition Sciences and Food Technology and National Nutrition and Food Technology Researc
Full name of responsible person
Dr. Seyed Hossein Davoodi
Street address
No 7, Hafezi st. Farahzadi Blvd., Sharake Qods
City
Tehran
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Faculty of Nutrition Sciences and Food Technology and National Nutrition and Food Technology Researc
Proportion provided by this source
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
Name of organization / entity
1) Cancer Research Center, Shahid Beheshti University of Medical Sciences 2) Department of Nutrition
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Person responsible for scientific inquiries

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Full name of responsible person
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Person responsible for updating data

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Full name of responsible person
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Other areas of specialty/work
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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