

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jan 2020

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

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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.

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

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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Email address

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 colorometric method

2

Description

Inflammatory biomarkers including high-sensitivity C-reactive protein (hs-CRP), Tumor necrosis factor alpha (TNF α), 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 metalloproteinase 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

Colorometric 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 Tajrish 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 Tajrish 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

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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 Research

Full name of responsible person

Dr. Seyed Hossein Davoodi

Street address

No 7, Hafezi st. Farahzadi Blvd., Sharake Qods

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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 Research

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***Phone**

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Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**1) Cancer Research Center, Shahid Beheshti
University of Medical Sciences 2) Department of
Nutrition**Full name of responsible person**

Dr. Seyed Hossein Davoudi

Position

Associate Professor

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Molecular Nutrition, Faculty of Nutrition Sciences and**Full name of responsible person**

Elham Kazemian

Position

PhD Candidate in Nutritional Sciences

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**Department of Basic Sciences and Cellular and
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Elham Kazemian

Position

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Other areas of specialty/work**Street address**

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Postal code**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*