

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 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 appoptosis 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.

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 23871

##### Email address

kazemianelham@sbmu.ac.ir

##### 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

#### 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**

##### 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 appoptosis 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/m<sup>2</sup>; 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 Food

**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 Survivor

**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 $\alpha$ ), Interleukin 6 (IL-6),  $\beta$ -Interferon (IFN- $\beta$ )

**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

Colorimetric 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

##### 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 Research

##### 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 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***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

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

No 7, Hafezi st. Farahzadi Blv, Shahrake Gharb

**City**

Tehran

**Postal code****Phone**

+98 21 2236 0662

**Fax****Email**

hdavoodi1345@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Department of Basic Sciences and Cellular and 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**

No 7, Hafezi st. Farahzadi Blv, Shahrake Gharb

**City**

Tehran

**Postal code****Phone**

+98 21 2236 0662

**Fax****Email**

kazemianelham@yahoo.com;

kazemianelham@sbm.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Department of Basic Sciences and Cellular and 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**

No 7, Hafezi st. Farahzadi Blv, Shahrake Gharb

**City**

Tehran

**Postal code****Phone**

+98 21 2236 0662

**Fax****Email**

kazemianelham@yahoo.com ;

kazemianelham@sbm.ac.ir

**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*