

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effect of vitamin D supplementation on serum 25-hydroxyvitamin D levels, inflammatory biomarkers and total antioxidant capacity in different types of vitamin D receptor polymorphisms in breast cancer women

Protocol summary

Summary

This study has been designed to evaluate the Effect of vitamin D supplementation on serum 25-hydroxyvitamin D levels, biomarkers of inflammation and total antioxidant capacity in different types of vitamin D receptor polymorphisms in breast cancer women. This study will be done as a double blind controlled randomized trial with a period of 8 weeks. Forty six subjects with cancer will be selected from Ahvaz Shafa Hospital. Inclusion Criteria are included all women who were diagnosed with stage I breast cancer; age>20; 23< BMI<30; not consuming any kinds of vitamin D supplements during last 3 months. Exclusion criteria are included a history of any types of cancer; people with chronic diarrhea and malabsorption; non-Iranian races. The subjects will be divided into 2 groups based on randomized block design. Group 1 will receive 50000 IU of vitamin D3 per week, group 2 will receive placebo per week. Serum levels of TNF- α , TGF- β , TAC and 25 (OH) D will be determine by taking blood samples at the baseline and at the end of the intervention. VDR gene polymorphisms (FOK1, BsmI1, Taq and Apa1) will be determined by SSP-PCR techniques. Anthropometric measurements (height, weight and waist circumferences) will be measured at the baseline and after 8 weeks of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090623924N1**

Registration date: **2015-10-08, 1394/07/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-08, 1394/07/16

Registrant information

Name

houra mohseni

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 33367543

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D supplementation on serum 25-hydroxyvitamin D levels, inflammatory biomarkers and total antioxidant capacity in different types of vitamin D receptor polymorphisms in breast cancer women

Public title

Effect of vitamin D supplementation on serum 25-hydroxyvitamin D levels, inflammatory biomarkers and total antioxidant capacity in different types of vitamin D receptor polymorphisms in breast cancer women

Purpose

Treatment

Inclusion/Exclusion criteria

all women who were diagnosed with stage I breast cancer; age > 20 years; 23 < BMI < 30; not consuming any kinds of vitamin D supplements during last 3 months; not getting any medication that affect serum vitamin D status. Exclusion criteria: the presence of any underlying disease (liver, kidney and HIV); a history of chemotherapy or radiotherapy for any reason except for current cancer; treatment with corticosteroids; pregnancy and lactation; chronic diarrhea and malabsorption; non-iranian races (foreigners).

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Highway, Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Postal code

15794

Approval date

2015-07-25, 1394/05/03

Ethics committee reference number

lr.ajums.rec.1394.253

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

C50.9

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Tumor Necrosis Factor alpha

Timepoint

At the beginning and the end of the study

Method of measurement

ELISA

2

Description

Transforming Growth Factor beta

Timepoint

At the beginning and the end of the study

Method of measurement

ELISA

3

Description

Total Antioxidant Capacity

Timepoint

At the beginning and the end of the study

Method of measurement

ELISA

4

Description

25 (OH) D

Timepoint

At the beginning and the end of the study

Method of measurement

ELISA

5

Description

vitamin D receptor polymorphisms (Fok1, Bsm1, Taq9, Apa1)

Timepoint

At the beginning of the study

Method of measurement

PCR

Secondary outcomes

1

Description

Antropometric Measurements (height, weight and waist circumferences)

Timepoint

at the baseline and after 8 weeks of intervention

Method of measurement

Height, hip and waist circumferences in cm and weight in kg by standard method

Intervention groups

1

Description

Placebo, one time per week for 2 months

Category

Placebo

2

Description

Vitamin D, 50,000 IU, one time per week for 2 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

Houra Mohseni, student of Master Science

Street address

Golestan, Shafa Hospital

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

DR. Ghadiri

Street address

Ahvaz, Golestan Highway, Jundishapur University of Medical Sciences

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Sciences

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

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Houra Mohseni

Position

Student of Master Science

Other areas of specialty/work

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Person responsible for scientific inquiries

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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