

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

The effect of cholecalciferol supplementation on serum levels of vascular endothelial growth factor-A and angiopoietin-2 in breast cancer patients co-administered with tamoxifen: a randomized controlled clinical trial

Protocol summary

Study aim

The effect of cholecalciferol supplementation on serum levels of vascular endothelial growth factor-A (VEGF-A) and angiopoietin-2 (ANG-2) in breast cancer (BC) patients treated with tamoxifen

Design

study population: women with BC treated with tamoxifen; sample size: 20 participants in each group; blinding: Triple blind; Participants, distributor of supplement and laboratory assessor will be blinded from the assignment in interventional groups; randomization: Blocked random allocation; single or multi central: Multi-central study involved oncology clinics, Hematology and Oncology Research Center (HORC) and Nour-Nejat hospital; study phase: 2.

Settings and conduct

Intervention: intervention group will consume a 50000 IU vitamin D capsule per week and placebo group will consume a soft-gel capsule that contain liquid paraffin per week similar in appearance (color, size and odor) for the duration of 8 weeks intervention.

Participants/Inclusion and exclusion criteria

The main inclusion criteria: Confirmed breast malignancy upon histopathologic reports ; Range of BMI 20 to 35 kg/m²; Age: 30 – 65 years; histopathologic grade of 2 and 3; co-administered with tamoxifen. The main exclusion criteria: being at clinical stage 4; pregnancy; lactation; acute renal or liver failure; using antiepileptic medications and contraceptive drugs; history of hormonal related diseases (such as diabetes, hyperthyroidism and poly cystic ovary syndrome); having nausea, vomiting, headache and vertigo.

Intervention groups

Intervention and placebo groups

Main outcome variables

Measurement of serum levels of VEGF-A and ANG-2 at baseline and the endpoint of intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082111335N6**

Registration date: **2015-12-27, 1394/10/06**

Registration timing: **prospective**

Last update: **2018-11-12, 1397/08/21**

Update count: **2**

Registration date

2015-12-27, 1394/10/06

Registrant information

Name

Saeed Pirouzpanah

Name of organization / entity

Nutrition Faculty, Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences.

Expected recruitment start date

2016-01-25, 1394/11/05

Expected recruitment end date

2018-03-16, 1396/12/25

Actual recruitment start date

2016-01-25, 1394/11/05

Actual recruitment end date

2018-03-16, 1396/12/25

Trial completion date

2018-05-17, 1397/02/27

Scientific title

The effect of cholecalciferol supplementation on serum levels of vascular endothelial growth factor-A and angiopoietin-2 in breast cancer patients co-administered with tamoxifen: a randomized controlled clinical trial

Public title

The effect of cholecalciferol supplementation on angiogenic factors in breast cancer survivors co-administered with tamoxifen

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The range of body mass index (BMI) is 20 to 35 kg/m² 30 - 65 years old histopathologic confirmed breast malignancy histopathologic grades of 2 and 3 tendency to participate in study completed questionnaire tamoxifen consumption

Exclusion criteria:

Being at clinical stage 4 pregnancy lactation acute renal or liver failure using antiepileptic medications and contraceptive drugs history of hormonal related diseases (such as diabetes, hyperthyroidism and poly cystic ovary syndrome) nausea vomiting headache vertigo

Age

From **30 years** old to **65 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **40**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Block random allocation was performed using a statistical software program

Blinding (investigator's opinion)

Triple blinded

Blinding description

Eligible patients were randomly assigned to the intervention and placebo groups. Packages containing cholecalciferol capsules were encoded in B and C to ensure that there is uninformed status for grouping in this study. Sampling in two groups of intervention and placebo was done by Random allocation software. Checking the eligibility of the participants and placing in the intervention and placebo groups was done by researcher who was unaware of the grouping and the type of supplements that they received during the study.

The intervention group received 50000 IU cholecalciferol per week and the placebo group received capsules containing liquid paraffin that they were similar in appearance, size, color, and odor to cholecalciferol capsules. Patients, researcher and laboratory staff were unknown to the distribution of cholecalciferol and placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Research Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Attar Neyshabori St.,

City

Tabriz

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51665118

Approval date

2015-09-16, 1394/06/25

Ethics committee reference number

TBZMED.REC.1394.518

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

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

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

Serum levels of angiopoietin-2 and VEGF-A

Timepoint

Baseline and 8 week after baseline

Method of measurement

ELISA

Secondary outcomes

1

Description

Anthropometric parameters

Timepoint

Baseline and 8 week after baseline

Method of measurement

Waist circumference, body mass index (kg/m²), and waist to hip ratio

Intervention groups

1

Description

Intervention group: supplement therapy with a soft-gel of 50000 IU cholecalciferol(vitamin D) per week for 8 weeks the duration of intervention. The soft-gel produced by Zahravi pharmaceutical.

Category

Treatment - Drugs

2

Description

Placebo: Placebo soft-gel typically similar to vitamin D soft-gel in size, color and odor. BC patients will use a soft-gel that contain liquid paraffin every week for the duration of 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Oncology Clinics, Hematology and Oncology Research Center, Noor-Nejat hospital

Full name of responsible person

Zahra Shahveghar-Asl

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Hafez st, Azadi Blvd, Noor-Nejat hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad-Reza Rashidi

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Grant name

Grant code / Reference number

TBZMED.REC.1394.518

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

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Saeed Pirouzpanah

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Just a part of data can share.

When the data will become available and for how long

6 months after publication

To whom data/document is available

There is no limitation.

Under which criteria data/document could be used

There is no limitation.

From where data/document is obtainable

E-mail: pirouzpanah@gmail.com

What processes are involved for a request to access data/document

After sending a written request via e-mail, the files will be sent.

Comments