Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of vitamin D3 supplementation (cholecalciferol) on nutritional status, VDR gene expression, endocrine, metabolic, and adipokine parameters in patients with benign breast tumors:Randomized controlled clinical trial

Protocol summary

Study aim

Determination of the effect of vitamin D3 (cholecalciferol) supplementation on nutritional status, gene expression, VDR, endocrine parameters, metabolic parameters, and adipokines in patients with benign breast tumors

Design

The patients will be classified into two intervention groups (receivers of vitamin D and placebo receivers of oral liquid paraffin) based on age, BMI, and benign type (fibrocystic masses and fibroadenomas), provided that they have no malignant characteristics confirmed by ultrasound examination.

Settings and conduct

The current study is a randomized controlled clinical trial. Random sampling will be conducted using a random number table, and the selected samples will be allocated to each block and group. The study will be conducted in a triple-blind manner.

Participants/Inclusion and exclusion criteria

Inclusion criteria:histopathological evidence of BBT,age between 19 and 50 years,serum vitamin D deficiency,at least two years since diagnosis, willingness to cooperate and complete the informed consent form. Exclusion criteria:Malabsorption disorders,biliary tract obstruction, acute or chronic conditions, hyperthyroidism, hormonal disorders,type 1 diabetes, hypoglycemia,grade 3 obesity,a daily calorie intake of less than 500 or more than 3500 kcal/d,cystectomy,asthma, any benign lesions in other organs, pregnancy and lactation,chemotherapy,radiotherapy, or hormone therapy, use of glucocorticoid, anti-seizure, contraceptive, and HRT medications,fish liver oil more than 2000 mg per day،caffeinated pain reliever

Intervention groups

In the intervention group, patients will receive one pearl of vitamin D3 50,000 IU per week for 8 weeks. In the control group, patients will receive one pearl of oral liquid paraffin per week for 8 weeks.

Main outcome variables

nutritional status, VDR gene expression, endocrine, metabolic, and adipokine parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100209003320N24**
Registration date: **2024-07-18, 1403/04/28**
Registration timing: **registered_while_recruiting**

Last update: **2024-07-18, 1403/04/28**
Update count: **0**

Registration date

2024-07-18, 1403/04/28

Registrant information

Name

Mehrangiz Ebrahimi mamagani

Name of organization / entity

Health & Nutrition faculty of Tabriz university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2024-07-05, 1403/04/15
Expected recruitment end date
2024-11-05, 1403/08/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of vitamin D3 supplementation (cholecalciferol) on nutritional status, VDR gene expression, endocrine, metabolic, and adipokine parameters in patients with benign breast tumors:Randomized controlled clinical trial

Public title
The effect of vitamin D3 on benign breast tumor
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Histopathological evidence of BBT (fibrocystic, fibroadenoma, etc.) Age between 19 and 50 years At least two years since diagnosis willingness to cooperate and complete the informed consent form Serum vitamin D deficiency (less than 20 ng/ml)
Exclusion criteria:
Malabsorption disorders (such as Crohn's disease, celiac disease), biliary tract obstruction Acute or chronic conditions (including various types of cancer, liver, kidney, and acute heart failure), hyperthyroidism, hormonal disorders prior to diagnosis (e.g., polycystic ovary syndrome (PCOS)), type 1 diabetes, hypoglycemia, adrenal gland disorders Grade 3 obesity A daily calorie intake of less than 800 or more than 3500 kcal/d Asthma Any benign lesions in other organs Pregnancy Lactation Chemotherapy Radiotherapy Hormone therapy Cystectomy surgery Use of glucocorticoid, anti-seizure, contraceptive, and HRT medications Consuming more than 2000 mg of cod liver oil Taking painkillers containing caffeine
Age
From **19 years** old to **50 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be classified into two intervention groups (receivers of vitamin D and placebo receivers of oral liquid paraffin) based on age, BMI, and benign type (fibrocystic masses and fibroadenomas), provided that they have no malignant characteristics confirmed by ultrasound examination. Random sampling will be conducted using a random number table, and the selected samples will be allocated to each block and group.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The study is designed as a triple-blind trial. Initially, random selection of the samples is conducted by the study designer, and a list is prepared. Then, the clinic staff, who are unaware of the allocation at the time of enrollment, execute this list. Participants are randomly assigned to two groups: those receiving the vitamin D supplement and those receiving the placebo (oral liquid paraffin). Blinding procedure: Participants: Are unaware of the type of supplement they receive (vitamin D or paraffin). Clinic staff: Responsible for delivering the supplements and placebos, and the packages are delivered in a uniform manner without any distinguishing labels. Laboratory personnel: Who analyze the test results, are unaware of the participants' group allocations. The supplement and placebo packages are prepared and distributed uniformly without any indication of their contents. Allocation codes are kept with the principal investigator until the end of the study, and none of the individuals involved in the study's execution are aware of these codes to minimize bias.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Tabriz University of Medical Sciences
Street address
Central Building of Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran
City
Tabriz
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East Azarbaijan
Postal code
5166/15731
Approval date
2024-06-12, 1403/03/23

Ethics committee reference number
IR.TBZMED.REC.1403.183

Health conditions studied

1

Description of health condition studied
Benign breast disease
ICD-10 code
D24
ICD-10 code description
Benign neoplasm of breast

Primary outcomes

1

Description
VDR gene expression
Timepoint
Before the start of the intervention, 8 weeks after the start of the intervention (end of the intervention)
Method of measurement
Real time RT-PCR

2

Description
Endocrine parameters
Timepoint
Before the start of the intervention, 8 weeks after the start of the intervention (end of the intervention)
Method of measurement
ELIZA

3

Description
Metabolic parameters
Timepoint
Before the start of the intervention, 8 weeks after the start of the intervention (end of the intervention)
Method of measurement
Enzymatic kits

4

Description
Adipokines
Timepoint
Before the start of the intervention, 8 weeks after the start of the intervention (end of the intervention)
Method of measurement
ELIZA

Secondary outcomes

1

Description
Nutritional status
Timepoint
Before the start of the intervention, 8 weeks after the start of the intervention (end of the intervention)
Method of measurement
A 24-hour dietary recall in three days (one holiday and two working days) and valid food frequency questionnaire

2

Description
Physical activity
Timepoint
Before the start of the intervention, 8 weeks after the start of the intervention (end of the intervention)
Method of measurement
Physical activity questionnaire

3

Description
Anthropometric status
Timepoint
Before the start of the intervention, 8 weeks after the start of the intervention (end of the intervention)
Method of measurement
Centimeter, Scale

Intervention groups

1

Description
Intervention group:Consume one pearl of vitamin D3 50,000 IU per week for 8 weeks. Participants will be advised to maintain their usual lifestyle, including their habitual diet.All participants will begin a two-week run-in period before starting the intervention. During this period, participants are asked not to be exposed to direct sunlight for more than 15 minutes a day. Also, they are asked not to consume eggs more than twice a week. Patients are also advised to avoid sources of omega-3 oils, nuts (such as almonds and walnuts), fatty fish, and cod liver. Avoid foods containing methylxanthine, vitamin E supplement, evening primrose oil during this period and until the end of the study.All participants will receive calcium carbonate (500 mg) together with cholecalciferol (200 IU) (Ca/VitD) from the beginning to the end of the study
Category
Treatment - Other

2

Description
Control group: One pearl of oral liquid paraffin per week for 8 weeks. In the control group, patients will receive one pearl of oral liquid paraffin per week for 8 weeks. The appearance of the placebo capsules will be identical to the vitamin D capsules in terms of color, shape, size, and packaging. Both vitamin D and placebo capsules will be obtained from Zahravi Pharmaceutical Company.Participants will be advised to maintain their

usual lifestyle, including their habitual diet.All participants will begin a two-week run-in period before starting the intervention. During this period, participants are asked not to be exposed to direct sunlight for more than 15 minutes a day. Also, they are asked not to consume eggs more than twice a week. Patients are also advised to avoid sources of omega-3 oils, nuts (such as almonds and walnuts), fatty fish, and cod liver. Avoid foods containing methylxanthine, vitamin E supplement, evening primrose oil during this period and until the end of the study.All participants will receive calcium carbonate (500 mg) together with cholecalciferol (200 IU) (Ca/VitD) from the beginning to the end of the study.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz University of Medical Sceinces

Full name of responsible person
Dr. Mehrangiz Ebrahimi-Mamagani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name
Tabriz University of Medical Sciences

Grant code / Reference number

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
Dr. Mehrangiz Ebrahimi- Mameghani

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Data collected for the primary outcomes will be shared.

When the data will become available and for how long
The access period starts 12 months after the results are published

To whom data/document is available
The data will be available only to people working in scientific institutions

Under which criteria data/document could be used
The data of this study will be available to other researchers only for meta-analysis studies

From where data/document is obtainable
Sanaz Asemani, email adress:asemanisanaz65@gmail.com Phon number: 09038553148

What processes are involved for a request to access data/document
The applicant should provide a brief description of the aims and methods of Meta-analysis. His/her request will be assessed and, if agreed, the data will be emailed to the applicant. All these procedures will take no longer than 15 days.

Comments