

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of vitamin D on mammographic breast density in women older than 40 years. years

Protocol summary

Summary

The aim of this study is to determine the effect of vitamin D on mammographic breast density in women older than 40 years. This clinical trial, double-blind, placebo-controlled, single center study is conducted in Arash Women's Hospital. Among women older than 40 years, 1084 women are randomly participated in this study. Exclusion criteria: Women who have contraindications for consuming vitamin D; history of breast cancer; Hormonal therapy and oral contraceptives in the last 3 months; Pregnant women; Women who consumed vitamin D supplement in the last 6 months. First, breast density of participants are evaluated with clinical breast examination and were recorded as low or high density. Then the breast density is measured and classified (<25%, 25-50%, 50-70%, >75%) with the bilateral mammography by a radiologist. Then the participants are divided randomly into two groups. Intervention in group 1 include: Tablet vitamin D 50,000 IU, monthly, for 2 years. Intervention in group 2 (placebo group) include: tablet vitamin E 400 IU, monthly, for 2 years. Breast density of all participants are evaluated with breast clinical examination every 6 month and every year with mammography for two years. Finally the rate of breast density are compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904154329N1**

Registration date: **2012-09-28, 1391/07/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-09-28, 1391/07/07

Registrant information

Name

Sadaf Alipour

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-11-16, 1390/08/25

Expected recruitment end date

2015-01-15, 1393/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D on mammographic breast density in women older than 40 years. years

Public title

The effect of vitamin D on breast density in women older than 40 years

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: women older than 40 years who have Indications for mammography. Exclusion criteria: Women

who have contraindications for consuming vitamin D;
History of breast cancer; Hormonal therapy and oral
contraceptives in the last 3 months; Pregnant women;
Women who consumed vitamin D supplement in the last
6 months.

Age

From **41 years** old to **90 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **1084**

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**

Tehran University of Medical Sciences ,Deputy of
Research.

Street address

Qods St, Keshavarz Blvd

City

Tehran

Postal code**Approval date**

2011-11-16, 1390/08/25

Ethics committee reference number

10530

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

Breast density

ICD-10 code

-

ICD-10 code description

-

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

The rate of breast density

Timepoint

Every 6 months with clinical examination and every year
with mammography for 2 years

Method of measurement

Mammography , Clinical examination

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention Groups: Tablet vitamin D (50,000 IU),
monthly for 2 years.

Category

Treatment - Drugs

2**Description**

Control Groups: Tablet vitamin E (400 IU), monthly ,for 2
years.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Arash Women 's Hospital

Full name of responsible person

Sadaf Alipour,Assistant Professor of Surgery

Street address

Arash Women 's Hospital, Rashid Ave, Resalat
Highway, Tehranparse,Tehran.Iran

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences , Deputy of
Research

Full name of responsible person

D.r Akbar Fotohi

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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

Tehran University of Medical Sciences , Deputy of Research

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

Arash Women 's Hospital,Tehran University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor of Surgery

Other areas of specialty/work

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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