

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effect of Vit D on AMH level and ovarian reserve in female breast cancer patients who have been treated with chemotherapy

Protocol summary

Study aim

The effect of Vit D on AMH level and ovarian reserve in 18-40 years old female breast cancer patients who have been treated with chemotherapy between 1397-1398 in Imam Khomeini hospital.

Design

Type of study: phase 3 Randomized clinical trail In this study 18-40 years old female breast cancer patients will be randomized in 2 groups. age,number of pregnancies, fertility status, menstrual disorders, smoking history, type of surgery and cancer stage will be documented. Before chemotherapy, AMH level will be documented for all patients. One group will be administered with 1000 IU daily calcitriol during and till six month after chemotherapy. The second group will not take vitamin D. The AMH level falls immediately after chemotherapy and will gradually improved during chemotherapy and fully recover after 3-6 month of chemotherapy.The AMH level will be measured before, at the end and 6 month after chemotherapy. all measurements will be in the same lab and with the same manner.

Settings and conduct

Female breast cancer patients between 18-40 years old undergoing neoadjuvant or adjuvant chemotherapy between 1397-1398 in cancer institute of Imam Khomeini hospital will be participated in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Chemotherapy candidate breast cancer patients between 18-40 years-old Exclusion criteria: GNRH agonist treatment during or after chemotherapy Positive history of cytotoxic therapy Bilateral salpyngo-oophorectomy surgery EF<50%

Intervention groups

Patients who receive daily vit D from beginning of chemotherapy to 6 months after that considering to randomization.

Main outcome variables

AMH level 6 month after chemotherapy ending.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180718040514N1**

Registration date: **2019-03-12, 1397/12/21**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-12, 1397/12/21**

Update count: **0**

Registration date

2019-03-12, 1397/12/21

Registrant information

Name

Zahra Dastmardi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3366 0399

Email address

Zdastmardi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-27, 1397/09/06

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Vit D on AMH level and ovarian reserve in female breast cancer patients who have been treated with chemotherapy

Public title

The effect of Vit D on AMH level and ovarian reserve in 18-40 years old female breast cancer patients who have been treated with chemotherapy between 1397-1398 in Imam Khomeini hospital.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chemotherapy candidate Breast cancer patients between 18-40 years- old.

Exclusion criteria:

History of cytotoxic treatment GNRH agonist treatment during or after chemotherapy EF<50% Positive history for BSO(bilateral salpingo-oophorectomy)

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Referred patients are randomized to 2 groups. One receive daily vit D (1000 IU) and other group receive no drug.

Blinding (investigator's opinion)

Single blinded

Blinding description

The analysers are not informed about randomization groups, ,patients and analyser are informed due to lack of placebo in study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional research ethics committee Imam Khomeini hospital

Street address

Tehran , Keshavarz BLVD,Imam Khomeini hospital

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2018-11-27, 1397/09/06

Ethics committee reference number

IR.TUMS.IKHC.REC.1397.237

Health conditions studied

1

Description of health condition studied

Infertility due to breast cancer chemotherapy.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

AMH level before ,immediately after and 6 month after chemotherapy.

Timepoint

Before chemotherapy , immediately after chemotherapy and 6 month after end of chemotherapy.

Method of measurement

ELISA technique in central Imam Khomeini laboratory.

Secondary outcomes

empty

Intervention groups

1

Description

In this study 18-40 years old female breast cancer patients will be randomized in 2 groups. patients with history of cytotoxic therapy or BSO will be excluded.age,number of pregnancies, fertility status,menstrual disorders, smoking history, type of surgery and cancer stage will be documented.Before chemotherapy,AMH level will be documented for all patients. One group will be administered with 1000 IU daily calcitriol during and till six month after chemotherapy.The second group will not take vitamin D.The AMH level falls immediately after chemotherapy and will gradually improved during chemotherapy and fully recover after 3-6 month of chemotherapy.The AMH level will be measured before, at the end and 6 month after chemotherapy. all measurements will be in the same lab and with the same manner.

Category

Treatment - Drugs

2

Description

Control group: the group that receive no drug.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Radiotherapy oncology clinics of institute cancer in Imam Khomeini hospital

Full name of responsible person

Zahra Dastmardi

Street address

Tehran , Keshavarz BLVD, Imam Khomeini hospital ,institute cancer.

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Email

zdastmardi@razi.tums.ac.ir

2

Recruitment center

Name of recruitment center

Haematology oncology clinic institute cancer ImamKhomeini hospital

Full name of responsible person

Dr Zahra Zastmardi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Tehran university of medical science

Street address

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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

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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Dastmardi

Position

Resident of radiotherapy oncology

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Not to diminish patients data.

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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