Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 calciteriol 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 calciteriol 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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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
Tehran , Keshavarz BLVD, Imam Khomeini hospital ,institute cancer.
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Email
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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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Person responsible for scientific

inquiries

Contact

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Person responsible for updating data

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Position
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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