Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effects of 4 months of 25 Hydroxy vitamin D3 supplementation and probiotics independently and concomitantly on some factors affecting cancer progression in patients with breast cancer undergoing surgery referred to Shahid Bahonar Hospital in Kerman.

Protocol summary

Study aim

The effects of probiotic and 25-hydroxy vitamin D3 consumption in breast cancer patients.

Design

A double-blind clinical trial (patient and physician) with four intervention groups randomized by the factorial method.

Settings and conduct

The trial will be performed in the hematology and oncology ward of Shahid Bahonar Hospital in Kerman. Patients who meet the inclusion criteria will be randomly assigned to one of four intervention groups. The physician and patient are blinded, and patients will receive the intervention for four months, and the primary and secondary outcomes will be assessed at the beginning and the end of the study.

Participants/Inclusion and exclusion criteria

Women over 18 years old who have Breast Cancer Stage III, II (luminal A, luminal B, Her2 ENRICHED) are approved histopathologically and treated with neoadjuvant and surgical treatment.

Intervention groups

Intervention group 1: One daily capsule of 25 hydroxy vitamin D 3 1000 IU daily with probiotic placebo capsule for 4 months Intervention group 2: One probiotic capsule daily, plus one vitamin D placebo capsule for 4 months. Intervention group 3: One probiotic capsule daily 1000000000 CFU plus one 25 hydroxy vitamin D 3 1000 IU capsule for 4 months. Intervention group 4: one probiotic placebo capsule daily and one vitamin D3 placebo capsule for 4 months.

Main outcome variables

Main outcome variables: 1. Miller-Payne Grade 2. RCB Score 3. Ki-67

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200313046756N1**
Registration date: **2020-03-28, 1399/01/09**
Registration timing: **prospective**

Last update: **2020-03-28, 1399/01/09**
Update count: **0**

Registration date

2020-03-28, 1399/01/09

Registrant information

Name
Vahid Maazed
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 34 1223 5019
Email address
maazed@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-08, 1399/01/20

Expected recruitment end date

2021-04-09, 1400/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effects of 4 months of 25 Hydroxy vitamin D3 supplementation and probiotics independently and concomitantly on some factors affecting cancer progression in patients with breast cancer undergoing surgery referred to Shahid Bahonar Hospital in Kerman.

Public title
Vitamin D, Probiotics and Breast Cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women over 18 years with clinical stage II and III breast cancer diagnosis. Undergoing Neo-adjuvant Treatment and Surgery.
Exclusion criteria:
Age less than 18 years Stages I and IV of Breast Cancer BMI >30 Non-surgical advanced or metastatic cancers Cancer with a Basal-like Molecular Pattern Patients who have been taking vitamin D or probiotic supplements for the past three months. People with hyperparathyroidism or hypoparathyroidism active Kidney stones in the past six months Renal Failure (Creatinine> 190mmol / L) Hypercalcemia History of taking part in other intervention tests. Hormone therapy history. History of radiotherapy Recent use of estrogenic drugs such as birth control pills Chronic diarrhea or constipation (over 4 consecutive weeks) History of inflammatory bowel disease Celiac disease, chronic pancreatitis, history of colectomy and ileostomy History of gallstones Liver Failures Known cases of AIDS Continuous and long-term use of antibiotics, consumption of aluminum hydroxate History of Thiazide diuretics
Age
From **18 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into four intervention groups by the factorial method. Randomization Method: Factorial Randomization Unit: Person Randomization Tool: Random Number Table
Blinding (investigator's opinion)
Double blinded
Blinding description
People will be kept blind. 1. Patients: Each patient will receive a label according to the random number table that will appear on the patient's drug box. Medicines do not differ in appearance, taste, odor. The patient consumes two capsules daily. 2. Physician: The analyzing team will give the medicine boxes to the physician, and the physician will provide the medication based on the random number table.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Kerman University of Medical Sciences
Street address
Beginning of Ibn Sina Street, First of Jihad Boulevard, Somayeh intersection (Tahmasb Abad)
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2020-03-10, 1398/12/20
Ethics committee reference number
IR.KMU.REC.1398.709

Health conditions studied

1

Description of health condition studied
Breast Cancer
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Measurement of Miller-Payne Grade Index on Residual Tumor Tissue
Timepoint
4 months after intervention
Method of measurement
Microscopic examination

2

Description
Residual Cancer Burden Score on residual tumor tissue

Timepoint
4 months after intervention
Method of measurement
By http://www.mdanderson.org/breastcancer_RCB.

3

Description
Ki-67 nuclear protein as a biomarker of cell proliferation
Timepoint
At the beginning of the intervention, by Core needle biopsy and 4 months later (after surgery) on the residual tumor tissue
Method of measurement
Immunohistochemical staining

Secondary outcomes

1

Description
Serum IL-1 beta
Timepoint
On the first day of the intervention and 4 months after the intervention
Method of measurement
enzyme-linked immunosorbent assay(ELISA)

2

Description
Serum IL-6
Timepoint
On the first day of the intervention and 4 months after the intervention
Method of measurement
ELISA

3

Description
Serum IL-10
Timepoint
On the first day of the intervention and 4 months after the intervention
Method of measurement
ELISA

4

Description
Serum TNF alpha
Timepoint
On the first day of the intervention and 4 months after the intervention
Method of measurement
ELISA

Intervention groups

1

Description
Intervention group: Patients receiving vitamin D3 at a dose of 1000 IU daily as a single oral capsule, with food, and with a probiotic placebo capsule for 16 consecutive weeks from breast cancer diagnosis until surgery.
Category
Treatment - Drugs

2

Description
Intervention group: Patients who receive single probiotics capsule daily at 1 billion CFU before meals with a single vitamin D3 placebo capsule for at least 16 weeks from cancer diagnosis until surgery
Category
Treatment - Drugs

3

Description
Intervention group: Patients receiving vitamin D3 at a dose of 1000 IU daily as a capsule, with food and probiotic capsules daily with 1 billion CFU for 16 consecutive weeks from breast cancer diagnosis until surgery.
Category
Treatment - Drugs

4

Description
Intervention group: Patients who receive one vitamin D3 placebo capsule with food and one probiotic placebo capsule daily before meals for 16 consecutive weeks from breast cancer diagnosis until surgery
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Bahonar Hospital
Full name of responsible person
Ali Asghar Tirgar
Street address
Kerman Province, Kerman, Qaraney St
City
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7616913555
Phone
+98 34 3223 5011
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Web page address
http://bh.kmu.ac.ir/fa

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr. Abbas Pardakhty
Street address
Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran
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Kerman
Postal code
7616913555
Phone
+98 34 3132 5856
Email
abpardakhty@kmu.ac.ir
Web page address
http://kmu.ac.ir/fa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman University of Medical Sciences
Proportion provided by this source
75
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

2

Sponsor
Name of organization / entity
Zist Takhmir Pharmaceutical Company
Full name of responsible person
Mohammad Fattah
Street address
No. 597, Heydar Khani Crossroad, Farajam Street, Resalat Square
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Phone
+98 21 7749 5007
Fax
+98 21 7713 2961
Email
info@zisttakhmir.ir
Web page address
http://zisttakhmir.com/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Zist Takhmir Pharmaceutical Company
Proportion provided by this source
25
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Ali Asghar Tirgar
Position
Medical Student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Full name of responsible person
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masoudrezaei082@gmail.com

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
Not applicable
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data will be initially de-identified. 1. Demographic Data of Participants: These data will generally be included in a table in the article. 2. Main outcome data: The article will be appended to the article in charts and tables as well as in an Excel file. Secondary outcome data in the article will be attached to the article in graphs and tables as well as in an Excel file.
When the data will become available and for how long
Starting data access period six months after the results are published
To whom data/document is available
Data will be available only to researchers working in academic and scientific institutions approved by the Ministry of Health
Under which criteria data/document could be used
The data will be available to researchers for further statistical analysis
From where data/document is obtainable
Refer to the person responsible for the project's scientific accountability to access the data
What processes are involved for a request to access data/document
Applicants will submit a personal resume and the purpose of the data to the person responsible for the scientific accountability of the plan. The responsible person will be required to investigate the request within one week of sending the researcher information.
Comments