Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

The Effects of synbiotic supplementation in reducing of Chemotherapy-induced side effects in women with Breast Cancer

Protocol summary

Study aim
The effect of synbiotic supplementation on reducing chemotherapy-induced side effects in women with breast cancer(BC)

Design
Randomization is done in the form of random blocks of volume 4 and the random list is compiled by statistical software. Randomization and blinding are performed to maintain concealment.This is in the 3 phases of clinical trial.

Settings and conduct
This study will be a 6-weeks triple-blind randomized clinical trial in patients with BC undergoing chemotherapy admitted to the internal ward of Firoozegar Hospital.No changes in physical activity or diet are expected.

Participants/Inclusion and exclusion criteria
inclusion: definitive diagnosis of BC; one-day chemotherapy courses; Stage 1 to 3 of BC; History of complications following previous sessions; no history of GI problems before BC; History of at least 1 and at last 2 previous sessions of chemotherapy; Do not consuming probiotic dairies or any foods containing probiotic or prebiotic, or their supplements in the past 2 weeks; age 18 years and older; Willingness to cooperate exlusion: Chronic diseases such as HTN, CHD, stroke, liver and renal failure, impaired cell count and GI problems; BMI>30; History of tumor in other organs or metastasis; taking medicines or other treatments to reduce nausea(Except for the usuals); Severe GI problems during the study; Neutropenic patients: Consumption of probiotic dairies or any food containing probiotic or prebiotic,or their supplements during the study; Recent history of infection or use of antibiotics in the past 3 months; radiation therapy and chemotherapy simultaneously; not willing to continue

Intervention groups
int-group and cont-group will receive a synbiotic supplement and placebo twice a day for 6weeks, respectively.

Main outcome variables
Experience and severity of nausea, vomiting, diarrhea, constipation, pain, fatigue ,anorexia, Sleep quality and mental-emotional status

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20091114002709N56**
Registration date: **2021-05-05, 1400/02/15**
Registration timing: **prospective**

Last update: **2021-05-05, 1400/02/15**
Update count: **0**

Registration date
2021-05-05, 1400/02/15

Registrant information

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Farzad Shidfar

Name of organization / entity
Iran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-22, 1400/03/01

Expected recruitment end date
2022-03-21, 1401/01/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effects of synbiotic supplementation in reducing of Chemotherapy-induced side effects in women with Breast Cancer

Public title
The Effects of synbiotic supplementation in reducing of Chemotherapy-induced side effects in women with Breast Cancer
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of breast cancer by oncologist and pathologist Receiving one-day chemotherapy courses Stage 1 to 3 of breast cancer (pre-metastatic stages) History of complications following previous chemotherapy sessions no history of gastrointestinal problems before breast cancer at least one and at last two previous sessions of chemotherapy Do not consuming probiotic dairy products or any foods containing probiotic or prebiotic compounds, or their supplements in the past two weeks. Age 18 years and older Willingness to cooperation
Exclusion criteria:
Chronic diseases such as hypertension, coronary heart disease, history of stroke, liver failure (ALT and AST levels > 100 IU / L), renal failure (serum creatinine levels > 1.7 mg / dl), impaired cell count (WBC > 20,000 U / L, hemoglobin less than 10 mg / dl, platelets <15,000 / mcL or >400,000 / mcL) and gastrointestinal problems Body mass index >30 kg / m2 History of tumor in other organs or metastasis to other organs taking medicines or other treatments to reduce nausea (Except for the usual anti-nausea and vomiting medicines) Severe gastrointestinal problems and complications during the study Neutropenic patients Consumption of probiotic dairy products or any foods containing probiotic or prebiotic compounds, or their supplements during the study Recent infection or recent use of antibiotics in the past three months Receiving radiation therapy and chemotherapy simultaneously Not willing to continue cooperation
Age
From **18 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by the restricted randomization method: first people in terms of age (18 to 40 years and 40 to 70 years) and body mass index (18.5 to 24.9 and 25 to 29.9) in quadratic blocks (A, B, C and D) will be placed. Then, random allocation of people in each block to intervention and control groups will be done. random allocation of individuals to intervention and control groups, will be performed by means of software.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This study will be triple-blinded, so that information analysts, researchers and all participants are unaware of intervention and control groups. While one of the classmates unrelated to the project is aware of the study groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Hemat Express way, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2021-04-18, 1400/01/29
Ethics committee reference number
IR.IUMS.REC.1400.050

Health conditions studied

1

Description of health condition studied
chemotherapy-induced side effects
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Experience and severity of nausea
Timepoint
One hour before receiving chemotherapy drugs in the first, second and third visit
Method of measurement
McGill Nausea and Vomiting Questionnaire

2

Description
Experience and severity of vomiting
Timepoint
One hour before receiving chemotherapy drugs in the first, second and third visit
Method of measurement
McGill Nausea and Vomiting Questionnaire

3

Description
Experience and severity of diarrhea
Timepoint
One hour before receiving chemotherapy drugs in the first, second and third visit
Method of measurement
Bristol Diarrhea and Constipation Scale

4

Description
Experience and severity of constipation
Timepoint
One hour before receiving chemotherapy drugs in the first, second and third visit
Method of measurement
Bristol Diarrhea and Constipation Scale

5

Description
Experience and severity of fatigue
Timepoint
One hour before receiving chemotherapy drugs in the first, second and third visit
Method of measurement
CFS questionnaire

6

Description
Experience and severity of chemotherapy-induced pain
Timepoint
One hour before receiving chemotherapy drugs in the first, second and third visit
Method of measurement
McGill Pain Questionnaire

7

Description
sleep quality
Timepoint
One hour before receiving chemotherapy drugs in the first, second and third visit
Method of measurement
PSQL questionnaire

8

Description
Experience and severity of anorexia
Timepoint
One hour before receiving chemotherapy drugs in the first, second and third visit
Method of measurement
FAACT questionnaire

9

Description
Psycho-emotional status
Timepoint
One hour before receiving chemotherapy drugs in the first, second and third visit
Method of measurement
PHQ-9 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will be given two capsules of lactocare synbiotic daily for 6 weeks. Lactocare Synbiotic Capsules are manufactured by Zist Takhmir Company .Lactocare is an oral capsule containing high levels of beneficial bacteria (Lactobacilli, Bifidobacteria and Streptococcus) with prebiotic fructo-oligosaccharide (contributing to growth and probiotic activity)
Category
Rehabilitation

2

Description
Control group: Patients consume two placebo capsules twice a day for 6 weeks. Placebo capsules Are produced by Zist Takhmir company
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Internal ward of Firoozgar Hospital
Full name of responsible person
Ḍr Ali Basi
Street address
Firoozgar Hospital, Beh Afarin St, Karim Khan St, Valiasr Square
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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
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
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Farzad SHidfar
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Person responsible for updating data

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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
Some of the data will be shared, such as information about the main consequences and etc.
When the data will become available and for how long
The access period will be 6 months after publication of the results
To whom data/document is available
The obtained data from current study will be available only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
Six months after the publication of the papers from this study, the data obtained will be available to the applicant researchers for further analysis
From where data/document is obtainable
Applicants can be contacted with correspond author by e-mail or postal address to receive the requested data. Postal address: Nutrition department, School of health, Iran University of Medical Sciences, Hemmat expressway, Tehran Phon number:0098 21 8862 2755 E-mail: Farzadshidfar@yahoo.com
What processes are involved for a request to access data/document
Applicants will be able to access the obtained data from current study by sending an email to the corresponding author, after a maximum of one week
Comments