

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
exclusion: 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

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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shidfar.f@iums.ac.ir

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

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Hemat Express way, Iran University of Medical Sciences

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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

Dr Ali Basi

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Firoozgar Hospital, Beh Afarin St, Karim Khan St,
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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Full name of responsible person

Farzad SHidfar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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)**

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