Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The effect of probiotics on quality of life and inflammatory and oxidative stress biomarkers in patients undergoing breast cancer chemotherapy

Protocol summary

Study aim
The aim of this study was to determine the effects of probiotic supplementation on quality of life, inflammatory factors, and oxidative stress biomarkers in patients undergoing breast cancer chemotherapy.

Design
Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers. 60 patients with breast cancer of eligible in the study will be selected. Patients will be assigned to receive either probiotic supplements and placebo.

Settings and conduct
Patients with breast cancer and referred to Day hospital, Tehran, Iran.

Participants/Inclusion and exclusion criteria
The inclusion criteria were patients with ages between 20 and 80, breast cancer without metastases, they are candidates for chemotherapy for the first time after surgery or before surgery, Breast cancer has just been diagnosed in the patient. The exclusion critria were consuming probiotic supplements within 8 weeks prior to the study, taking other forms of probiotics including probiotic yogurt and other fermented foods, taking antioxidants supplements, patients with metabolic syndrome, patients with chronic infections.

Intervention groups
Patients will be assigned to receive either probiotic supplements (intervention group: n=30) and placebo (control group: n=30).

Main outcome variables
Quality of Life, gastrointestinal symptom, blood factors, inflammatory factors and biomarkers of oxidative stress will be measured at study baseline and end-of-trial

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191006045001N1**
Registration date: **2020-01-26, 1398/11/06**
Registration timing: **retrospective**

Last update: **2020-01-26, 1398/11/06**
Update count: **0**

Registration date
2020-01-26, 1398/11/06

Registrant information

Name
Mahtab sadat Miraftab

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 5534 4047

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miraftab.mahtab@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-30, 1398/08/08

Expected recruitment end date
2019-12-30, 1398/10/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of probiotics on quality of life and inflammatory and oxidative stress biomarkers in patients undergoing breast cancer chemotherapy

Public title
The effect of probiotics in treatment of patients undergoing breast cancer chemotherapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Breast cancer without metastases Patients candidate for chemotherapy for the first time after surgery or before surgery. Breast cancer just diagnosed
Exclusion criteria:
Consuming probiotic supplements within 8 weeks prior to the study Taking other forms of probiotics including probiotic yogurt and other fermented foods Taking antioxidants supplements Patients with metabolic syndrome Patients with chronic infections
Age
From **20 years** old to **80 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants were randomly assigned to receive either probiotic (n = 30) or placebo (n = 30) based on randomized block randomization. Blocks of size 2, 4 and 6 are used. Rand software was used for randomization. Closed envelopes were used to hide the randomization process, which were opened at the time of patient's visit to minimize the gap between randomization and drug or placebo.
Blinding (investigator's opinion)
Double blinded
Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses will be completed. Another person who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8715988141
Approval date
2019-07-28, 1398/05/06
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1398.048

Health conditions studied

1

Description of health condition studied
breast cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Quality of life of patients
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
patient health Questionnaire 9

Secondary outcomes

1

Description
Gastrointestinal disorders
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Clinical examination by oncology specialist

2

Description
Anemia
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement

CBC test (hemoglobin<10g/dl)

3

Description
Leukopenia
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
CBC test (white blood cell<4000)

4

Description
Thrombocytopenia
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
CBC test (Platelet<100000)

5

Description
Nitric oxide
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

6

Description
high sensitivity C-reactive protein
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

7

Description
Glutathione
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

8

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

Intervention groups

1

Description
Intervention group: Probiotic capsule containing 4 strains of Bifidobacterium lactis (1/8×109 units per gram), Lactobacillus acidophilus (1/8×109 units per gram), Bifidobacterium bifidum (1/8×109 units per gram) G), Bifidobacterium langum (1/8×109 units / g) daily, orally for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: placebo capsules, daily, orally for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Oncology clinic of Day hospital
Full name of responsible person
Dr Masoud Fakharian
Street address
Day hospital, Valiasr Ave, Tehran, Iran
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8718695511
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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
Kashan 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
Day hospital, Tehran
Full name of responsible person
Dr Masoud Fakharian Kashani
Position
Hematology and Oncology Specialist
Latest degree
Subspecialist
Other areas of specialty/work
Hematology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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