Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of synbiotic supplementation on the serum concentration of anti-inflammatory factors and adiponectin in the survivors of Breast Cancer with Lymphedema

Protocol summary

Summary

Specific objective of this study is The effect of synbiotic supplementation on the serum concentration of anti-inflammatory factors and adiponectin in the survivors of Breast Cancer with Lymphedema. Method: randomized, double blind, consumption of placebo in control group, single center. participants : Breast cancer survivors with Lymphedema. Inclusion criteria: Women with unilateral Breast Cancer Related Lymphedema; breast cancer lymphedema in STAGE = 2; age range of 18-60 years; BMI between 25 and 35; At least one month has passed since the last treatment such as radiotherapy Exclusion criteria : Cancer recurrence during the study; Failure to follow a weight loss diet; Consumption of food and supplements containing probiotics during the study; Incidence of edema-like diseases such as renal, cardiovascular and respiratory failure during the study period; Metastasis; Infectious diseases in Study length; Consumption of less than 56 capsules of 70 capsules at the end of the study . Sample size of this study is 88 persons (44 individuals in intervention group and 44 individuals in control group) Intervention in this study is consumption of symbiotic supplement consists of (Lactobacillus casei, Lactobacillus Rhamnosus, Lactobacillus Bulgaricus, Bifidobacterium breve, Bifidobacterium langum, Streptococcus thermophilus + Fructooligosacharide) microbal population : 1010 CFU/gr and 38/5 mg fructooligosaccharide, once daily for 10 weeks in breast cancer survivors with low calorie diet. Primary outcome of this study is change in fasting serum IL-10 and secondary outcomes are change in VEGF, TGF-β and adiponectin

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017092023861N6**
Registration date: **2017-09-26, 1396/07/04**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-09-26, 1396/07/04

Registrant information

Name
Mitra Zarrati

Name of organization / entity
Iran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 8670 4814

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zarrati.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Science

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of synbiotic supplementation on the serum concentration of anti-inflammatory factors and adiponectin in the survivors of Breast Cancer with Lymphedema

Public title

The effects of synbiotic supplementation on anti inflammatory index in lymphedema after breast cancer treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Women with unilateral Breast Cancer Related Lymphedema; breast cancer lymphedema in STAGE = 2; age range of 18-60 years; BMI between 25 and 35; At least one month has passed since the last treatment such as radiotherapy; willingness to participate in the study Non-inclusion criteria: use of multi-vitamin minerals and omega-3 supplements up to 1 month before the study began; acute and chronic infection; history of autoimmune diseases such as rheumatoid arthritis; Inflammatory diseases such as heart failure, pulmonary, kidney and diabetes; taking supplements of probiotics from 6 months before study; having a weight loss diet in Length 6 months before the study; Smoking and alcohol consumption; Lymphedema due to other cancers Exclusion criteria : Unwillingness of the patient to continue research collaboration; No subsequent referral; Cancer recurrence during the study; Failure to follow a weight loss diet; Consumption of food and supplements containing probiotics during the study; Incidence of edema-like diseases such as renal, cardiovascular and respiratory failure during the study period; Metastasis; Infectious diseases in Study length; Consumption of less than 56 capsules of 70 capsules at the end of the study

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

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

Iran University Of Medical Sciences, next to the Milad hospital, the intersection of Sheikh Fazlallah and Shahid Chamran, Hemmat expressway

City

Tehran

Postal code

1449614535

Approval date

2017-07-17, 1396/04/26

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9511468007

Health conditions studied

1

Description of health condition studied

Lymphedema

ICD-10 code

C50.9

ICD-10 code description

Primary outcomes

1

Description

IL-10

Timepoint

Before and after the intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

TGF-β

Timepoint

Before and after the intervention

Method of measurement

ELISA

2

Description

VEGF

Timepoint

Before and after the intervention

Method of measurement

ELISA

3

Description
Adiponectin
Timepoint
Before and after the intervention
Method of measurement
ELISA

4

Description
BMI
Timepoint
Before and after the intervention
Method of measurement
Weight ratio (kg) to squared height (m)

5

Description
skin fold thickness
Timepoint
Before and after the intervention
Method of measurement
caliper

6

Description
Waist
Timepoint
Before and after the intervention
Method of measurement
Meter (cm)

7

Description
Waist to hip ratio
Timepoint
Before and after the intervention
Method of measurement
Calculate

8

Description
Nutrition status
Timepoint
Before and after the intervention
Method of measurement
Measurement of energy and nutrients intake using a 24-hour dietary recall questionnaire and anthropometric indices using scales and measurements

9

Description
Volume of lymphedema
Timepoint
Before and after the intervention
Method of measurement
water tank technique

10

Description
physical activity
Timepoint
Before and after the intervention
Method of measurement
IPAQ questionnaire

Intervention groups

1

Description
Intervention group: Weight loss diet consultation (At the beginning of the study all the participants, according to their age, height, weight and calculating Energy Expenditure , should follow the weight loss diet which results in reduction in body weight about 0.5 to 1 kg per week. Calorie intake of participants is calculated base on Mifflin Formula. The recommended amount of calories from each nutrient during the day will be based on : carbohydrates 65-55%, fat 35-20% and protein 15-10% of the calories) + consumption of synbiotic supplement consists of (Lactobacillus casei, Lactobacillus Rhamnosus, Lactobacillus Bulgaricus, Bifidobacterium breve, Bifidobacterium langum, Streptococcus thermophilus + Fructooligosacharide) microbal population : 1010 CFU/gr and 38/5 mg fructooligosaccharide, once daily for 10 weeks. symbiotic supplement will be purchase from Zist takhmir company.
Category
Treatment - Drugs

2

Description
Control group : weight loss diet consultation (At the beginning of the study all the participants, according to their age, height, weight and calculating Energy Expenditure , should follow the weight loss diet which results in reduction in body weight about 0.5 to 1 kg per week. Calorie intake of participants is calculated based on Mifflin Formula. The recommended amount of calories from each nutrient during the day will be based on : carbohydrates 65-55%, fat 35-20% and protein 15-10% of the calories) + placebo consists of (lactose,Magnesium Stearate, talk, silicon dioxide) once daily for 10 weeks. Placebo will be purchase from Zist takhmir company.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Seyed Khandan physiotherapy clinic
Full name of responsible person
Mitra Zarrati

Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Iran University of Medical Sciences
Full name of responsible person
Seyed Ali Javad Moosavi, Assistant of Research and Technology , Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, next to the Milad hospital, the intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemmat expressway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences, School of Public Health
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Position
Assistant Professor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty

Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty