Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of synbiotic supplementation on the serum concentration of inflammatory cytokines and leptin in Breast Cancer survivors with Lymphedema

Protocol summary

Summary

Specific objective of this study is The effect of synbiotic supplementation on the serum concentration of inflammatory cytokines and leptin in Breast Cancer survivors 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 between 18 to 60 years; BMI between 25 to 35 Kg/m2 ; At least one month has passed since the last treatment such as radiotherapy. Exclusion criteria: Cancer recurrence during the study; Metastasis; Diseases leading to edema such as renal, cardiopulmonary and pulmonary failure during the study; Infectious diseases during the study; Consumption of food and supplements containing probiotics during the study; Failure to follow the weight loss diet; Consumption less than 56 capsules. 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 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 in breast cancer survivors with low calorie diet. Primary outcome of this study is Tumor necrosis factor alpha and secondary outcomes are interleukin 1 ; interleukin 6 ; hsCRP and leptin.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017092023861N7**
Registration date: **2017-10-25, 1396/08/03**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-10-25, 1396/08/03

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
Email address
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 inflammatory cytokines and leptin in Breast Cancer survivors with Lymphedema

Public title
The effect of synbiotic supplementation on inflammation in Breast Cancer survivors with Lymphedema

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: women with unilateral breast cancer related lymphedema ; breast cancer lymphedema in stage 2; Age range between 18 to 60 years ; BMI between 25 to 35 Kg/m2 ; At least one month has passed since the last treatment such as radiotherapy; Willingness to participate in the study ; Non-inclusion criteria: Use of multivitamin minerals and omega 3 supplements up to 1 month before the study began; Inflammatory diseases such as heart failure, pulmonary, kidney and diabetes; autoimmune diseases such as rheumatoid arthritis; Acute and chronic infection; taking Probiotics supplementation 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: Cancer recurrence during the study; Metastasis; Diseases leading to edema such as renal, cardiopulmonary and pulmonary failure during the study; Infectious diseases during the study; Consumption of food and supplements containing probiotics during the study; Failure to follow the weight loss diet; Consumption less than 56 capsules; Unwillingness to continue cooperation

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
For randomization, the permuted block randomization will be used with quadruple blocks. According to the sample size of 88 identified, 22 blocks will be produced using the online site (www.sealedenvelope.com). In order to apply the concealment in the randomization process, unique codes will be used on the pharmaceutical boxes, which will be generated by the software. By entering each individual into a study based on the sequence produced, the packet of the drug in which the code is registered will be assigned to the individual. During the research, the random list has been provided to the statistics consultant and patients, executor of plan and everybody who takes part in measuring indicators will not be informed of the assigned groups.

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 1396.9511468008

Health conditions studied

1

Description of health condition studied
lymphedema

ICD-10 code
C50.9

ICD-10 code description
Breast, unspecified

Primary outcomes

1

Description
Tumor necrosis factor alpha

Timepoint
Before intervention and 10 weeks after the start of intervention

Method of measurement
ELISA

Secondary outcomes

1

Description
interleukin 1

Timepoint

Before intervention and 10 weeks after the start of intervention

Method of measurement

ELISA

2

Description

interleukin 6

Timepoint

Before intervention and 10 weeks after the start of intervention

Method of measurement

ELISA

3

Description

leptin

Timepoint

Before intervention and 10 weeks after the start of intervention

Method of measurement

ELISA

4

Description

hsCRP

Timepoint

Before intervention and 10 weeks after the start of intervention

Method of measurement

immunoturbidimetry

5

Description

volume of lymphedema

Timepoint

Before intervention and 10 weeks after the start of intervention

Method of measurement

water tank technique

6

Description

BMI

Timepoint

Before intervention and 10 weeks after the start of intervention

Method of measurement

Weight ratio (kg) to squared height (m)

7

Description

waist circumference

Timepoint

Before intervention and 10 weeks after the start of intervention

Method of measurement

meter

8

Description

waist to hip ratio

Timepoint

Before intervention and 10 weeks after the start of intervention

Method of measurement

Calculate

9

Description

skinfold thickness

Timepoint

Before intervention and 10 weeks after the start of intervention

Method of measurement

caliper

10

Description

Nutritional status

Timepoint

Before intervention and 10 weeks after the start of intervention

Method of measurement

Measurement of energy and nutrients intake using 24-hour dietary recall method and anthropometric measurement using scale and stadiometer

11

Description

Physical Activity

Timepoint

Before intervention and 10 weeks after the start of 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) + 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. synbiotic 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) + placebo consists of (lactose,Magnesium Stearate, talk, silicon dioxide) once daily for 10 weeks. Placebo will be purchase from Zist takhmir company.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Seyed Khandan physiotherapy clinic

Full name of responsible person
Dr Mitra Zarrati

Street address
Fourth Unit, Second Floor, Building 17, next to Kalantari, South Aboozar St, Khajeh Abdollah Ansari St, Seyed khandan Bridge.

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor of research, Iran University of Medical Science

Full name of responsible person
Seyed Ali Javad Moosavi, Assistant of Research and Technology , Iran University of Medical Sciences

Street address
Faculty of Nutrition, School of Public Health, 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 of research, Iran University of Medical Science

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 Science

Full name of responsible person
Dr Mitra Zarrati

Position
Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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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