# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Jul 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)
**Phone**
+98 21 8670 4814
**Email address**
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**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**
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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**
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**

**Street address**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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**Fax**
**Email**
saeideh.sv90@yahoo.com
**Web page address**

## 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*