

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 + Fructooligosaccharide) microbial 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)

Phone

+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 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 + Fructooligosaccharide) microbial 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

Fax

Email

zarrati.m@iums.ac.ir

Web page address

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

Full name of responsible person

Mitra Zarrati

Position

Assistant Professor

Other areas of specialty/work

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

Postal code

Phone

+98 21 8670 4814

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mitra Zarrati

Position

Assistant Professor

Other areas of specialty/work

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

Postal code

Phone

+98 21 8670 4814

Fax

Email

zarrati.m@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University Of medical sciences

Full name of responsible person

Ali Saneei Totmaj

Position

MS.c student in Nutrition Science

Other areas of specialty/work

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

Postal code

Phone

00

Fax

Email

saneei.ast@gmail.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