

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Effect of symbiotic supplement on serum insulin , IGF-1 and some sex hormones concentration in obese and overweight breast cancer survivors with low calorie diet

Protocol summary

Summary

Specific objective of this study is Effect of symbiotic supplement on serum insulin, IGF-1 and some sex hormones concentration in obese and overweight breast cancer survivors with low calorie diet. Method : randomized, double blind, consumption of placebo in control group, single center. participants : Breast cancer survivors. Inclusion criteria : 1- Female breast cancer survivors (or Cessation of menstruation for at least 6 months prior to chemotherapy); 2- Age range (50-75); 3- BMI = 25 - 40 Kg/m²; 4- At least one month has passed since the last radiotherapy; 5- Complete treatment of stage 1 - 4 breast cancer survivors; 6- Type of breast cancer : ER/PR+ and HER2-; 7- Willingness to cooperate and sign a written informed consent Exclusion criteria : 1- Metastasis during the study; 2- Failure to follow the weight loss diet; 3-Consumption less than 46 capsules of 56 capsules at the end of study; 4-Infectious disease during the study; 5- Consumption of probiotic foods during the study; 6- Consumption of fibre supplement during the study; 7- Consumption of herbal supplement; 8- Patient at any time can leave the study freely Sample size of this study is 76 persons (38 individuals in intervention group and 38 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 8 weeks in breast cancer survivors with low calorie diet. Primary outcome of this study is change in fasting serum insulin and secondary outcomes are change in estradiol, testosterone, DHEA-S, IGF-1, SHBG and IGFBP-3.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090223861N1**
Registration date: **2017-02-01, 1395/11/13**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-02-01, 1395/11/13

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

2017-04-09, 1396/01/20

Expected recruitment end date

2017-12-11, 1396/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of symbiotic supplement on serum insulin , IGF-1 and some sex hormones concentration in obese and overweight breast cancer survivors with low calorie diet

Public title

Effect of symbiotic supplement on breast cancer recurrence

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : 1- Female breast cancer survivors (or Cessation of menstruation for at least 6 months prior to chemotherapy); 2- Age range (50-75); 3- BMI = 25 - 40 Kg/m²; 4- At least one month has passed since the last radiotherapy; 5- Complete treatment of stage 1 - 4 breast cancer survivors; 6- Type of breast cancer : ER/PR+ and HER2-; 7- Willingness to cooperate and sign a written informed consent
Non-inclusion criteria: 1- History of Diabetes, acute heart failure, cirrhosis hepatic, acute and chronic renal failure; 2- History of autoimmune and infectious disease; 3- Have a weight loss diet during the 6 months prior to study; 4- Smoking; 5- Alcohol consumption; 6- Nutrition supplement consumption
Exclusion criteria : 1- Metastasis during the study; 2- Failure to follow the weight loss diet; 3-Consumption less than 46 capsules of 56 capsules at the end of study; 4- Infectious disease during the study; 5- Consumption of probiotic foods during the study; 6- Consumption of fibre supplement during the study; 7- Consumption of herbal supplement; 8- Patient at any time can leave the study freely

Age

From **50 years** old to **75 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

use of stratified randomization based on BMI (BMI=25-30 and BMI=30-40)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Science

Street address

Martyr Hemmat Highway, the highway of Sheikh Fazlullah Nuri and martyr Chamran

City

tehran

Postal code

Approval date

2016-11-19, 1395/08/29

Ethics committee reference number

IR.IUMS.REC 1395.9411468005

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50-C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Concentration of fasting serum Insulin

Timepoint

Before intervention and 8weeks after the start of intervention

Method of measurement

Microunit/ml - Elisa method

Secondary outcomes

1

Description

Estradiol

Timepoint

Before intervention and 8 weeks after the start of intervention

Method of measurement

Pg/ml - Elisa method

2

Description

Insulin resistance

Timepoint

Before intervention and 8 weeks after the start of intervention

Method of measurement

Calculate by the formula

3

Description

Testosterone

Timepoint

Before intervention and 8 weeks after the start of intervention

Method of measurement

ng/ml - ELISA method

4

Description

DHEA-S

Timepoint

Before intervention and 8 weeks after the start of intervention

Method of measurement

Mg/ml - EILSA method

5

Description

SHBG

Timepoint

Before intervention and 8 weeks after the start of intervention

Method of measurement

nmol/ml - ELISA method

6

Description

IGF-1

Timepoint

Before intervention and 8 weeks after the start of intervention

Method of measurement

ng/ml - ELISA method

7

Description

IGFBP-3

Timepoint

Before intervention and 8 weeks after the start of intervention

Method of measurement

ng/ml - ELISA method

8

Description

HbA1c

Timepoint

Before intervention and 8 weeks after the start of intervention

Method of measurement

Biochemical method

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. Participants in both; intervention and control groups refer to the dietitian in the doctor najafi's clinic one time every four weeks to change their diet. Calorie intake of participants is calculated base on Harris-Benedict 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 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 8 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. Participants in both; intervention and control groups refer to the dietitian in the doctor najafi's clinic one time every four weeks to change their diet. Calorie intake of participants is calculated based on Harris-Benedict 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 8 weeks. Placebo will be purchase from Zist takhmir company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Safa Najafi Clinic

Full name of responsible person

Mahsa Raji Lahiji

Street address

Doctor's building number 3, unit 11, Molasadra Street, Vanak Square

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

Doctor seyed Javad ali Mosavai

Street address

Martyr Hemmat Highway, the highway of Sheikh Fazlullah Nuri and martyr Chamran

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

Mahsa Raji Lahiji

Position

Student / Nutrition master

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

PHD nutrition/ Science committee of Nutrition group

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Mahsa Raji lahiji

Position

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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