Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 + Fructooligosacharide) microbal 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, testostrone, 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

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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 chronin 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
Befor 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 + Fructooligosacharide) microbal 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
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Mahsa Raji Lahiji
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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