Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effect of symbiotic supplement on serum adiponectin, hs-CRP, TNF-α, Apo A1 and Apo-B100 concentration in obese and overweight breast cancer survivors with low calorie diet

Protocol summary

Study aim
Effect of symbiotic supplement on serum adiponectin, Apo A1, TNF-α, hs-CRP and Apo B100 concentration in obese and overweight breast cancer survivors with the low-calorie diet.

Design
randomized, double-blind, consumption of placebo in control group, single center

Settings and conduct
Recruiting and performing the study will take place in oncologist's clinic. participants are randomly divided into intervention and control groups. participants, researchers, and analyser are blinded about groups of study.

Participants/Inclusion and exclusion criteria
participants: Breast cancer survivors Main Inclusion criteria: 1- Female breast cancer survivors 2- Age range (50-75) 3- BMI = 25 - 40 Kg/m2 4- At least one month has passed since the last radiotherapy 5- Type of breast cancer ER/PR+ and HER2- Main 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 the study

Intervention groups
Intervention group: Participants in this group follow the weigh loss diet like control group. 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. Control group: weight loss diet + placebo

Main outcome variables
Primary outcome: Adiponectin Secondary outcomes: TNF-alpha; hs-CRP; Apo-A1, and Apo-B100

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20091114002709N49**
Registration date: **2018-05-18, 1397/02/28**
Registration timing: **prospective**

Last update: **2018-05-18, 1397/02/28**
Update count: **0**

Registration date
2018-05-18, 1397/02/28

Registrant information

Name
Farzad Shidfar

Name of organization / entity
Iran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-30, 1397/03/09

Expected recruitment end date

2018-11-30, 1397/09/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of symbiotic supplement on serum adiponectin, hs-CRP, TNF-α, Apo A1 and Apo-B100 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:

Female breast cancer survivors (or Cessation of menstruation for at least 6 months prior to chemotherapy) Age range (50-75) BMI = 25 - 40 Kg/m2 At least one month has passed since the last radiotherapy Complete treatment of stage 1 - 4 breast cancer survivors Type of breast cancer : ER/PR+ and HER2- Willingness to cooperate and sign a written informed consent

Exclusion criteria:

History of Diabetes, acute heart failure, cirrhosis hepatic, acute and chronic renal failure History of autoimmune and infectious disease weight loss diet during the 6 months prior to study Smoking Alcohol consumption Nutrition supplement consumption

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants, major researcher, data collectors were kept blind to study groups.

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 Science

Street address

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

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2018-04-20, 1397/01/31

Ethics committee reference number

IR.IUMS.REC1397.32557

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Adiponectin

Timepoint

Before intervention and 8 weeks after the start of intervention

Method of measurement

Elisa method

Secondary outcomes

1

Description

Tumor Necrosis Factor alpha (TNF-α)

Timepoint

Before intervention and 8 weeks after the start of intervention

Method of measurement
Elisa method

2

Description
high-sensitivity C-reactive protein (hs-CRP)
Timepoint
Before intervention and 8 weeks after the start of intervention
Method of measurement
Elisa method

3

Description
Apolipoprotein-A1 (Apo-A1)
Timepoint
Before intervention and 8 weeks after the start of intervention
Method of measurement
Elisa method

4

Description
Apolipoprotein-B100 (Apo-B100)
Timepoint
Before intervention and 8 weeks after the start of intervention
Method of measurement
Elisa method

Intervention groups

1

Description
Intervention group: 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
Dr Safa Najafi
Street address
Doctor's building number 3, unit 11, Molasadra Street, Vanak Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant Masters Selected Research Week

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mahsa Raji Lahiji

Position
Student / Nutrition master

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Other areas of specialty/work
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Latest degree
Bachelor

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
participants privacy security

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to

make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available