Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effects of the cardioprotective diet on prevention of the incidence of cardiotoxicity in patients with breast cancer receiving Anthracycline

Protocol summary

Study aim
Our goal is to investigate the effects of a heart-protecting diet on anthracycline-induced heart poisoning.

Design
a parallel-group randomized clinical trial, One-way blind

Settings and conduct
60 patients with breast cancer who are candidates for chemotherapy with anthracyclines +/- trastuzumab are referred to the Iranian medicine specialist at week 0 to receive a diet, which will be explained as a 1 hour workshop, and will also adjust and receive diet based on weight and calories. A visit at week 8 and answering questions is recommended. The study is single-blinded, so that diet forms and recommendations are placed in the same folders and given to patients, and patients do not know which group has received the cardioprotective diet.

Participants/Inclusion and exclusion criteria
Women age 18-65; Breast cancer (based on pathology response); Candidate for chemotherapy including anthracyclines +/- trastuzumab؛ Exclusion criteria: History of heart disorders; Change the chemotherapy regimen for any reason; Unwillingness to continue the study; Follow less than 70% of trained dietary recommendations; History of liver disease

Intervention groups
First of patients enrolled and have completed consent form, medical history is taken. All patients are screened for weight, height, blood pressure, and demographic information, and recorded tests. Both groups receive chemotherapy with anthracyclines +/- trastuzumab (Herceptin) and other routine recommendations and care. In addition to the above, the intervention group receives a heart-protective diet will receive

Main outcome variables
left ventricular ejection fraction; LV global longitudinal strain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131218015860N7**
Registration date: **2021-11-16, 1400/08/25**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-16, 1400/08/25**
Update count: **0**

Registration date
2021-11-16, 1400/08/25

Registrant information

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Name of organization / entity
School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center, Shahid Behe

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-11, 1400/08/20

Expected recruitment end date
2023-02-20, 1401/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effects of the cardioprotective diet on prevention of the incidence of cardiotoxicity in patients with breast cancer receiving Anthracycline

Public title
Evaluation of the effects of the cardioprotective diet on prevention of the incidence of cardiotoxicity

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Women age 18-65 Breast cancer (based on pathology response) Candidate for chemotherapy including anthracyclines +/- trastuzumab 25 ≤BMI ≤ 19 Willingness to participate in the study
Exclusion criteria:
History of heart failure History of coronary artery disease Symptoms of heart failure (functional shortness of breath, orthopedics, PND) Ejection Fraction less than or equal to 40 Use of beta-blockers or ACEI Change the chemotherapy regimen for any reason Unwillingness to continue the study Follow less than 70% of trained dietary recommendations History of liver disease (except grade 1 and 2 fatty liver) History of kidney disease (other than history of urinary stones) • History of depression (taking antidepressants) BMI greater than 25 and less than 19

Age
From **18 years** old to **65 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomization is first done by random sequence generation. A simple randomization method will be used to generate a random sequence. The method of simple randomization in this study is the use of a random number table. A random number table is a set of numbers that are generated without a specific pattern or order and in a completely random form and has become a table. In order to use the table of random numbers, we first preset the table to read the numbers (from left to right). Then the numbers are considered for the study groups so that even numbers will be considered for the experimental group and odd numbers will be considered for the control group. The second step is the concealment of the randomization allocation because the assigned group will not be specified before the individual is assigned. In this study, due to the fact that sampling is multicenter, the central randomization method will be used to hide the allocation. In this method, the random sequence is given to a person in the school of Traditional Medicine and sampling is performed in three centers. Based on the order in which the participants entered the study, the researcher contacted the mentioned person in the School of Traditional Medicine and asked about the random assignment of the participant to the experimental or control group. Communication methods include the use of telephone, SMS, fax, e-mail, and so on.

Blinding (investigator's opinion)
Single blinded

Blinding description
Blindness in this study is single blind. This means that patients receive similar packages and they do not know that the intervention group is receiving an extra sheet containing heart-protective dietary recommendations.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical Sciences
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Approval date
2021-08-15, 1400/05/24

Ethics committee reference number
IR.SBMU.RETECH.REC.1400.258

Health conditions studied

1

Description of health condition studied
cardiotoxicity in patients with breast cancer receiving Anthracycline

ICD-10 code
C00-C97

ICD-10 code description
Malignant Neoplasms

Primary outcomes

1

Description
left ventricular ejection fraction
Timepoint
In weeks 0, 8 and 18 from the beginning of the intervention
Method of measurement
Echocardiography

2

Description
LV global longitudinal Strain (GLS)
Timepoint
In weeks 0, 8 and 18 from the beginning of the intervention
Method of measurement
Echocardiography

Secondary outcomes

1

Description
Alteration of the cardiac marker troponin
Timepoint
Weeks 0, 8 and 18 from the beginning of the intervention
Method of measurement
blood test (Measurement of cardiac troponin enzyme). This enzyme is measured by the enzyme immunoassay method according to standard conditions with ELISA device and with a series of calibrated pipettes.

2

Description
Quality of Life
Timepoint
Weeks 0, 8 and 18 from the beginning of the intervention
Method of measurement
Quality of Life Questionnaire (EORTC - QOL Br23)

Intervention groups

1

Description
Intervention group: The recipient of the diet protects the heart. First, a history is taken of the patients who have entered the study and completed the consent form. All patients are evaluated for weight, height, blood pressure, and demographic information, and patient tests are recorded. Both groups will receive chemotherapy with anthracyclines +/- trastuzumab (Herceptin) and other recommendations and the usual care, in addition to the above, the experimental group will receive a diet rich in heart tonics. This diet is similar to the diet recommended by Mozaffarian, which uses foods that are recommended as heart protectors. Since there is no standard guideline or standard protocol to prevent cardiovascular complications, in this study, the recommended diet for the participants of the experimental group is based on the Mozaffarian proposed diet. Dr. Mozaffarian et al. - are nutritionists who have focused on cardiovascular health for many years and have conducted numerous epidemiological studies on nutrition and the prevention of cardiovascular disease - they suggest a nutrient-based diet as a healthy diet for the heart.
Category
Prevention

2

Description
Control group: Patients who have entered the plan and completed the consent form will have a history. All patients are evaluated for weight, height, blood pressure, and demographic information and tests are recorded. Both groups of chemotherapy with anthracyclines +/- trastuzumab (Herceptin) and other recommendations and care Receive the usual, the control group will not receive CpD.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Tajrish Hospital
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Sponsors / Funding sources

1

Sponsor
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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
School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center,Shahid Behes
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available