Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the Effect of nano-silymarin on preventing Anthracycline-Induced cardiotoxicity in patients with breast cancer

Protocol summary

Study aim
Evaluation of prophylactic effect of nano-silymarin in prevention of anthracycline induced cardiotoxicity in breast cancer chemotherapy

Design
This study is a randomized, double-blind, placebo-controlled study. A total of 104 patients will be randomly allocated in two groups of intervention and placebo (each group 52 patients).

Settings and conduct
One-hundred four consecutive breast cancer patients admitted to the oncologist office and planned antracycline-based chemotheraphy, if provide written informed consent will be enrolled in the study. Patients meeting inclusion/exclusion criteria will be randomized in 1:1 ratio to receive silymarin or placebo, two times daily. Trial will be commenced 7 days before starting chemotherapy and continued for 4 courses and at the end, the incidence of cardiotoxicity is evaluated and compared in two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women who affected with breast cancer Non-including criteria: the presence of cardiomyopathy; coronary heart disease; mitral valve disease; prior chemotherapy or radiotherapy; alcohol abuse; any contraindications to silymarin; Patients who take other cardiac medications such as angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, non-dihydropyridine calcium channel blockers, diuretics, statins or beta-blockers.

Intervention groups
Intervention group: sinalive 70mg twice daily after breakfast and dinner , oral, for 4 courses of chemotherapy

Main outcome variables
Echocardiographic evaluation includes measuring the LV end-diastolic (LVEDD) and end-systolic dimensions (LVESD), systolic and diastolic function, discharge fraction and longitudinal global strain for all patients at baseline, and endpoint of chemotherapy.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200408046990N17**
Registration date: **2024-12-22, 1403/10/02**
Registration timing: **registered_while_recruiting**

Last update: **2024-12-22, 1403/10/02**
Update count: **0**

Registration date
2024-12-22, 1403/10/02

Registrant information

Name
Sepideh Elyasi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3180 1588

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elyasis@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-21, 1403/10/01

Expected recruitment end date
2026-03-21, 1405/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigation of the Effect of nano-silymarin on preventing Anthracycline-Induced cardiotoxicity in patients with breast cancer

Public title
Investigation of the Effect of milk thistle in preventing cardiac complications of chemotherapy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18-65 y Patients with breast cancer who planned for antracycline-based chemotherapy Signing of informed consent by the patient

Exclusion criteria:
Presence of cardiomyopathy (dilated, restrictive or hypertro-phic) detected by baseline echocardiography History of hypersensitivity to silymarin or similar compounds Pregnancy and lactation Past medical history of coronary heart disease Moderate or severe aortic and/or mitral valve disease Prior chemotherapy or radiotherapy Alcohol abuse Patients on other cardiac medications such as angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, non-dihydropyridine calcium channel blockers, diuretics, statins or beta-blockers

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **104**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocked randomization using website https://www.sealedenvelope.com With the explanation that each block has 4 members and the shape of the blocks can be as follows: [ABAB], [ABBA, [AABB],[BBAA],[BABA][BAAB] Code A belongs to the intervention group and code B belongs to the control group. the mentioned website selects 26 blocks from Quadruple blocks and patients will be assigned to blocks in the order of entry into the study and finally 104 patients will enter the study

Blinding (investigator's opinion)
Triple blinded

Blinding description
The nano Silymarin and placebo capsule (prepared by Mashhad Pharmacy School) will be packaged in boxes with same appearance and delivered to the clinician. Patients who meet the inclusion criteria are selected by clinician to be included in the study and will receive a box filled with medication or placebo respectively. Patients will be evaluated during the treatment course by the physician. Data collection and analysis will be performed by the pharmacy student and the clinical pharmacist. All of them will be unaware patients' grouping until the end of the study and data analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Qureshi Building, Daneshgah street

City
Mashhad

Province
Razavi Khorasan

Postal code
1394491388

Approval date
2024-08-04, 1403/05/14

Ethics committee reference number
IR.MUMS.REC.1403.219

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
Left ventricular (LV) end-systolic and end-diastolic diameters (LVESD, LVEDD), systolic and diastolic function

Timepoint
Echocardiographic measurements including LVESD, LVEDD at baseline. and at 6-month after the start of chemoterapy

Method of measurement
Echocardiography measurements by a specialist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: sinalive 70mg twice daily after breakfast and dinner , oral, for 4 courses of chemotherapy
Category
Prevention

2

Description
Control group: Placebo capsule for Sinaliv, produced by Exir Nano Sina Company that produced Sinaliv capsules, two tablet daily after breakfast and dinner, for 4 courses of chemotherapy, oral
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Personal office of the oncologist
Full name of responsible person
Amir Amirabadi
Street address
Third floor- Razi doctors' building- Razi avenue- Emam Reza Hospital square- Mashhad
City
Mashhad
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Razavi Khorasan
Postal code
9188893539
Phone
+98 51 3855 3598
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amirabadia@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Faculty of Pharmacy, Ferdowsi University, Vakilabad Boulevard
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9138813944
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+98 51 3841 1538
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tafaghodim@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Sepideh Elyasi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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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
No more data are 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