

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 anthracycline-based chemotherapy, 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: silymarin 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

Email address

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 anthracycline-based chemotherapy Signing of informed consent by the patient

Exclusion criteria:

Presence of cardiomyopathy (dilated, restrictive or hypertrophic) 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 chemotherapy

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

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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
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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

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 scientific inquiries

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Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Sepideh Elyasi

Position

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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

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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Latest degree

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Other areas of specialty/work

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