Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of oral nano-silymarin formulation efficacy in prevention of hepatotoxicity induced by doxorubicin-cyclophosphamide chemotherapy regimen in patients with non-metastatic breast cancer

Protocol summary

Study aim

Evaluation of oral nano Silymarin formulation efficacy in prevention of hepatotoxicity induced by Doxorubicin containing chemotherapy regimen in patients with non-metastatic breast cancer

Design

This is a randomized triple-blind, parallel group clinical trial on 70 patients with non-metastatic breast cancer (35 patients in treatment group and 35 patients in placebo group).

Settings and conduct

This study will be performed on 70 non-metastatic breast cancer patients referring to Imam Reza Hospital, Mashhad, Iran. They whether will receive 2 nano silymarin 70 mg capsules for 4 courses in treatment group or 2 placebo capsules in placebo group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Non-metastatic breast cancer undergoes chemotherapy with a regimen containing doxorubicin after a mastectomy. 2. Age between 18 to 65 years 3. Signing the informed consent by the patient. Non-Inclusion criteria: 1. Viral hepatitis 2. History of allergy to Silymarin or other similar compounds 3. Pregnancy or lactation 4. Liver involvement grade 2 or higher based on liver ultrasound. Exclusion criteria: 1. Changing the chemotherapy regimen 2. The patient unwillingness for medication use.

Intervention groups

Intervention group: two of 70 mg nano Silymarin capsules daily (one capsule after breakfast and one capsule after dinner) during 4 courses of chemotherapy. Placebo group: two placebo capsules/day for 4 courses of chemotherapy (with same appearance of nano Silymarin capsule containing all nano Silymarin capsule ingredients except nano Silymarin)

Main outcome variables

liver enzymes serum level & ultrasound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200408046990N13**
Registration date: **2023-09-04, 1402/06/13**
Registration timing: **prospective**

Last update: **2023-09-04, 1402/06/13**
Update count: **0**

Registration date

2023-09-04, 1402/06/13

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

2023-09-23, 1402/07/01

Expected recruitment end date

2025-03-19, 1403/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of oral nano-silymarin formulation efficacy in prevention of hepatotoxicity induced by doxorubicin-cyclophosphamide chemotherapy regimen in patients with non-metastatic breast cancer

Public title
Evaluation of oral nano-silymarin formulation effect in prevention of liver damage induced by doxorubicin-cyclophosphamide chemotherapy regimen in patients with non-metastatic breast cancer

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18-65 y Patients with diagnosis of non-metastatic breast cancer who will be treated by doxurobicin after mastectomy Signing the written consent

Exclusion criteria:
Viral hepatitis History of hypersensitivity to silymarin or similar compounds Pregnancy and lactation Any kind of liver injury resulting in rise of liver enzymes or bilirubin to higher than upper limit normal Renal failure Concomitant use of heptotoxic agents or antioxidants

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **70**

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 18 blocks from Quadruple blocks and patients will be assigned to blocks in the order of entry into the study and finally 70 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
2023-05-20, 1402/02/30

Ethics committee reference number
IR.MUMS.REC.1402.075

Health conditions studied

1

Description of health condition studied
Non-metastatic breast cancer

ICD-10 code
C50

ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Serum level of hepatic transaminases

Timepoint
At the beginning of the study, 4 weeks after the beginning of study, at the end of study

Method of measurement
Serum level measurement by the laboratory

2

Description
Liver ultrasound to determine the stage of the fatty liver

Timepoint

At the beginning of the study and at the end of study

Method of measurement

Ultrasound evaluation

3

Description

Serum level of total and direct billirubin

Timepoint

At the beginning of the study, 4 weeks after the beginning of study, at the end of study

Method of measurement

Serum level measurement by the laboratory

4

Description

prothrombin time

Timepoint

At the beginning of the study, 4 weeks after the beginning of study, at the end of study

Method of measurement

Serum level measurement by the laboratory

5

Description

serum albumin level

Timepoint

At the beginning of the study, 4 weeks after the beginning of study, at the end of study

Method of measurement

Serum level measurement by the laboratory

6

Description

Serum level of alkalin phosphatase

Timepoint

At the beginning of the study, 4 weeks after the beginning of study, at the end of study

Method of measurement

Serum level measurement by the laboratory

Secondary outcomes

1

Description

Serum level of creatinine and urea

Timepoint

At the beginning of the study, 2 weeks after the beginning of study and at the end of study

Method of measurement

Serum level measurement by the laboratory

Intervention groups

1

Description

Intervention group: sinalive 70mg twice daily after breakfast and dinner , oral, for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule for sinalive, two tablet daily after breakfast and dinner, for 8 week, oral

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital, affiliated to Mashhad University of Medical Sciences

Full name of responsible person

Sepideh Elyasi

Street address

Imam Reza Sq.

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elyasis@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Mouhebati

Street address

Faculty of Medicine, Ferdowsi University, Vakilabad Boulevard

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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
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
Faculty of Pharmacy; Ferdowsi University; Vakilabad Boulevard

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Person responsible for updating data

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Sharing plan

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

Title and more details about the data/document
The findings will be published in an article. Study protocol and statistical analysis will be used for article publication.

When the data will become available and for how long
One year after the end of the study it will be published

and available in databases.

To whom data/document is available

If the funding sponsor allowed, the findings will be available for researchers, clinicians, and scientific centers.

Under which criteria data/document could be used

The other researchers can use our findings in their review articles and meta analysis.

From where data/document is obtainable

For this purpose, you can contact with Sepideh Elyasi, at Clinical Pharmacy Department, School of Pharmacy, Vakil Abad Aven., Mashhad, Iran. Email: elyasis@mums.ac.ir

What processes are involved for a request to access data/document

After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor within 2 weeks

Comments