

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the Effect of Curcumin on Preventing Anthracycline-Induced Cardiomyopathy in Patients with Breast Cancer - A Randomized Clinical Trial Study

Protocol summary

Study aim

Evaluation of prophylactic effect of curcumin in prevention of anthracycline induced cardiotoxicity in breast cancer chemotherapy

Design

This study is a randomized, double-blind, placebo-controlled study. a total of 40 patients will be randomly allocated in two groups of intervention and placebo.

Settings and conduct

Forty consecutive breast cancer patients admitted to the Reza oncology 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 curcumin or placebo. Trial will be commenced 7 days before starting chemotherapy and continued for 6 months 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 Exclusion criteria: the presence of cardiomyopathy; coronary heart disease; mitral valve disease; prior chemotherapy or radiotherapy; alcohol abuse; any contraindications to curcumin; 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: 20 patients in whom the Curcumin is given orally at a dose of 500 mg/day for 6 months.
Control group: 20 patients in whom placebo is given for 6 months.

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: **IRCT20190224042818N1**

Registration date: **2019-02-27, 1397/12/08**

Registration timing: **prospective**

Last update: **2019-02-27, 1397/12/08**

Update count: **0**

Registration date

2019-02-27, 1397/12/08

Registrant information

Name

Hassan Mehrad-Majd

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2694

Email address

mehradmajdh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2021-03-05, 1399/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Investigation of the Effect of Curcumin on Preventing Anthracycline-Induced Cardiomyopathy in Patients with Breast Cancer - A Randomized Clinical Trial Study

Public title
Investigation of the Effect of Curcumin in preventing complications of chemotherapy

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with breast cancer who planned for antracycline-based chemotherapy
Exclusion criteria:
presence of cardiomyopathy (dilated, restrictive or hypertro- phic) detected by baseline echocardiography
Past medical history of coronary heart disease Moderate or severe aortic and/or mitral valve disease
Prior chemotherapy or radiotherapy, Alcohol abuse
Any contraindications to Curcumin
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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Using Random Allocation Software, random blocks with different volumes of 4 to 8 randomly spaced two color papers are concealed in envelopes and delivered to the secretary at Chemotherapy Dept. The secretary will draw the first upper color paper from the envelope for each patient. The medication or placebo, which will be blind for the secretary, is delivered to the patient according to the color of the paper. The patients initials along with the color of paper will be recorded in a list for further tracking.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient, the secretary, the oncologist, and the echoman (cardiologist) will be blinded to the study.

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
Faculty of Medicine, Azadi Square, Pardis campus
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Approval date
2018-07-18, 1397/04/27
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1397.503

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: Nano-Comintern at a dose of 80 mg/day (Exir Nano Sina Co., Iran) is given orally form for 7 consecutive days before chemotherapy until 6 months later.

Category

Prevention

2

Description

Control group: placebo is commenced 7 days before starting chemotherapy and will be continued for 6 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Fatemeh Homaei Shandiz

Street address

Kohsangi Blvd, Mashhad

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2

Recruitment center

Name of recruitment center

Reza Radiotherapy & Oncology Center

Full name of responsible person

Mahdiyeh Dayani

Street address

Shahrak Gharb, Mashhad, Razavi Khorasan Province

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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

Deputy of Research and Technology of the University,
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Fax

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Email

vcresearch@mums.ac.ir

Web page address

<http://v-research.mums.ac.ir/index.php>

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

Hassan Mehrad-Majd

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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 information

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