Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 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 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 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 curcomin; 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)
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+98 51 3801 2694
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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 chemoterapy

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, No. 19, Daneshgah St.,

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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

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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 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