

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Study the preventive effect of Carvedilol therapy against Adriamycin-induced acute cardiotoxicity in breast cancer patients by measurement of myocardial deformation index

Protocol summary

Summary

Main Outcome: This study is aimed to investigate the protective effect of carvedilol on cardiac changes during chemotherapy with Adrimycin by using strain, strain rate echocardiography Design and setting: 70 breast cancer patients, who were being under chemotherapy with Adriamycin, were enrolled. Patients were randomly divided into two groups. In case group every patient was given 12.5 mg Carvedilol daily from 7 days before chemotherapy to 7 days after finishing the chemotherapy course. In control group patients were given placebo exactly same as Carvedilol in case group. 6 cycles of chemotherapy at 3-week intervals were performed. Strain and strain rate echocardiography were done before starting, 10 days after 3rd cycle and 10 days after 6th cycle of chemotherapy. Participants including major eligibility criteria: Breast cancer patients who are under chemotherapy with Adriamycin in Qaem center, Mashhad are enrolled. These patients have neither documented heart disease nor contraindication for beta blocker, and their cancer is not metastatic. Interventions: Carvedilol tab 12.5 mg daily Variables: Strain, strain rate indices in echocardiography

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013093012924N1**
Registration date: **2014-09-02, 1393/06/11**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-09-02, 1393/06/11

Registrant information

Name

Ahmad Tashakori Beheshti

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 915 517 7368

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tashakoriba851@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad university of medical sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the preventive effect of Carvedilol therapy against Adriamycin-induced acute cardiotoxicity in breast cancer patients by measurement of myocardial deformation index

Public title

Study the preventive effect of Carvedilol therapy against Adriamycin-induced acute cardiotoxicity in breast cancer patients by measurement of myocardial deformation index

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: breast cancer patients who are candidate for chemotherapy with adriamycin. Exclusion criteria: documented heart disease; history of radiation or chemotherapy for cancer; metastatic disease; atrial fibrillation; BMI more than 30; creatinin more than 2; EF less than 30%; pulmonary congestion; beta blocker contraindications; insulin dependent diabetes mellitus; major depression; suicide attempt; pregnancy

Age

To 65 years old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad university of medical sciences, ethics committee

Street address

Daneshghah Avenue, Ghoreishi building

City

Mashhad

Postal code

Approval date

2011-12-31, 1390/10/10

Ethics committee reference number

۸۹۱۹۷

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

C50.9

ICD-10 code description

Breast, unspecified

2

Description of health condition studied

heart failure

ICD-10 code

I50.0

ICD-10 code description

Congestive heart failure

Primary outcomes

1

Description

strain rate

Timepoint

before intervention, at the middle of intervention, after intervention

Method of measurement

echocardiography

Secondary outcomes

1

Description

complications of carvedilol

Timepoint

during intervention

Method of measurement

by taking history

Intervention groups

1

Description

Carvedilol tab 12.5 mg daily for 5 months during chemotherapy

Category

Treatment - Drugs

2

Description

placebo tab daily for 5 months during chemotherapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem educational, research and treatment center

Full name of responsible person

Street address

Ghaem hospital, Dr. shariati Square, beginning of
Ahmadabad Avenue, Mashhad-Iran

City

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Mashhad University of
Medical Sciences

Full name of responsible person

Mohsen tafaghodi

Street address

Ghoreishi building, Daneshgah avenue

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Mashhad University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

cardiovascular research center, mashhad university
of medical sciences

Full name of responsible person

Ahmad Tashakori Beheshti

Position

MD

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bakaiyanm851@mums.ac.ir

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty