

# 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 Adriamycin 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

##### Email address

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

**Other areas of specialty/work****Street address**

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**City**

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**Postal code****Phone**

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**Fax****Email**

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*