

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Assessment of Treatment with Carvedilol in Preventing Heart failure in breast cancer patients under treatment with herceptin or anthracyclines.

Protocol summary

Summary

The aim of this study is assessment of effect of prophylactic carvedilol on incidence of heart failure in patients with breast cancer receiving herceptin or anthracyclines. The study population is HER2 positive breast cancer patients. The sample volume is 50 patients. The study is double blind. Breast cancer patients are randomly divided into two groups using randomised permuted blocks. After baseline speckle tracking echocardiography, the intervention group will receive carvedilol with dose 6.25 mg two times a day for 3 months or up to the time when symptoms of heart failure would develop. The primary outcome is development of heart failure symptoms or reduction in LVEF at the end of 3 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042433619N1**

Registration date: **2017-07-05, 1396/04/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-05, 1396/04/14

Registrant information

Name

Saeed Nourian

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4483 5396

Email address

s-nourian@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Baqiatallah University of Medical Sciences.

Expected recruitment start date

2017-06-10, 1396/03/20

Expected recruitment end date

2018-01-01, 1396/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Treatment with Carvedilol in Preventing Heart failure in breast cancer patients under treatment with herceptin or anthracyclines.

Public title

Assessment the effect of Carvedilol in preventing Heart failure in breast cancer patients.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: breast cancer patients under treatment with herceptin or antracyclines. Exclusion criteria: EF less than 50%; Significant Valvular Heart Disease; GFR < 30ml/h/m²; Hepatic Failure; Contraindications for beta blockers; Symptoms of Heart Failure.

Age

No age limit

Gender

Female

Phase

Groups that have been masked*No information***Sample size**

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Method of randomization is randomised permuted blocks.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**Ethics committee of Baqiyatallah University of
Medical Sciences**Street address**

Mollasadra Street

City

Tehran

Postal code**Approval date**

2015-09-23, 1394/07/01

Ethics committee reference number

IR.BMSU.REC.1394.244

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 and Right Ventricle Function

Timepoint

3 months after treatment

Method of measurement

Speckle Tracking Echocardiography

Secondary outcomes

empty

Intervention groups**1****Description**Intervention group: Carvedilol 6.25 mg tablet, 12.5 mg
two times a day, for 3 months or until the time of heart
failure symptoms development.**Category**

Treatment - Drugs

2**Description**

Control group: No Drug

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Baqiyatallah Hospital

Full name of responsible person

Saeed Nourian

Street address

Mollasadra street

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Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice chancellor for research of Baqiyatallah University
of Medical Sciences**Full name of responsible person**

Doctor Alishiri

Street address

Mollasadra street.

City

Tehran

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding sourceVice chancellor for research of Baqiyatallah 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
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Full name of responsible person
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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