Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 anthracylines. 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 Siences

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 chanceller 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 than50%; 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

3

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 Ventricule 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

City

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 source

Vice 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
Baqiyatallah University of Medical Sciences
Full name of responsible person
Saeed Nourian
Position
Cardiologist
Other areas of specialty/work
Street address
Mollasadra street.
City
Tehran
Postal code
Phone
+98 21 8248 3347
Fax
Email
S-nourian@razi.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Baqiyatallah University of Medical Sciences
Full name of responsible person
Saeed Nourian
Position
Cardiologist
Other areas of specialty/work
Street address
Mollasadra street.
City
Tehran
Postal code
Phone
+98 21 8248 3347
Fax
Email
S-nourian@razi.tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Baqiyatallah University of Medical Sciences
Full name of responsible person
Saeed Nourian
Position
Cardiologist
Other areas of specialty/work
Street address
Mollasadra Street.
City
Tehran
Postal code
Phone
+98 21 8248 3253
Fax
Email
s-nourian@razi.tums.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