Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

assessment of prophylactic treatment with carvedilol in incidence of heart failure in patients with HER2 positive breast cancer receiving trastuzumab

Protocol summary

Summary

The aim of this study is assessment of effect of prophylactic carvedilol on incidence of heart failure in patients with HER2 positive breast cancer receiving herceptin. The inclusion criteria was all HER2 positive breast cancer patients who are candidate for receiving herceptin. The exclusion criteria was history of heart failure, concomitant anthracycline therapy,and history of coronary artery disease.The study population is HER2 positive breast cancer patients.The sample volume is 100 patients.The study is double blind.Patients are randomly divided into two groups.After baseline echocardiography,the case group will receive carvedilol and the control group will receive placebo 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: **IRCT2014112019840N1**
Registration date: **2015-02-21, 1393/12/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-02-21, 1393/12/02

Registrant information

Name
Alborz Sherafati
Name of organization / entity
Tehran university of medical sciences,Imam Khomeini hospital
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tehran university of medical sciences

Expected recruitment start date

2014-09-01, 1393/06/10

Expected recruitment end date

2015-12-01, 1394/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

assessment of prophylactic treatment with carvedilol in incidence of heart failure in patients with HER2 positive breast cancer receiving trastuzumab

Public title

Effect of carvedilol in preventing heart failure following herceptin therapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion:patients with HER2 positive breast cancer who are candidate for herceptin therapy Exclusion: history of systolic heart failure (EF<50), history of anthracycline therapy,contraindications for beta blockers, history of

coronary artery disease,symptoms of heart failure including orthopnea or PND or dyspnea on exertion

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

The randomization method is by randomized permuted blocks

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran university of medical sciences

Street address

Poursina street,18th of Azar avenue, Keshavarz blvd

City

Tehran

Postal code

Approval date

2014-06-20, 1393/03/30

Ethics committee reference number

9111171017

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

C50-C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

heart failure

Timepoint

3 months after administration of herceptin

Method of measurement

echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention:Tab Carvedilol 6.25-12.5 mg bid for 3 months or up to the time when symptoms of heart failure develop

Category

Treatment - Drugs

2

Description

Control:placebo with the same dose and duration of carvedilol therapy

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Alborz Sherafati

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research of Tehran university of medical scienses

Full name of responsible person

DR Yonesian

Street address

Imam Khomeini Hospital, Keshavarz blvd

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 of research of Tehran university of medical scienses
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
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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