

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 21 6693 9537

Email address

asherafati@student.tums.ac.ir

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 sciences

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 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**

Imam Khomeini hospital

Full name of responsible person

Alborz Sherafati

Position

resident of cardiology

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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*